

STATE AND CONSUMER SERVICES AGENCY DEPARTMENT OF CONSUMER AFFAIRS ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA **Licensing Committee**

DATE:

DECEMBER 6, 2006

TIME:

9:30 a.m. - 12:30 p.m.

PLACE: HILTON AIRPORT HOTEL & CONVENTION CENTER

Contact Person: Virginia Herold

(916) 574-7911

2500 Hollywood Way

Burbank CA 91505 (818) 843-6000

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

accommodation by contacting Candy Place at (916) 574-7912, at least five working days before the meeting.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order 9.30 a.m.

- 1. Proposed Regulation Requirements for Pharmacies that Compound Medication —Amendments to 16 CCR sections 1716.1 and 1716.2 and adoption of sections 1735 - 1735.8
- 2. Update: Request to Add the Exam for the Certification of Pharmacy Technicians Developed by the Institute for the Certification of Pharmacy Technicians as a Qualification Method for Pharmacy Technician Registration
- 3. California Schools of Pharmacy Proposal to Identify and Agree on the Professional Competencies that Should Be Achieved by the End of Basic Internship Experiences
- 4. Request to Amend 16 CCR Section 1728 to Increase the Number of Intern Hours That Can Be Earned Outside a Pharmacy from 600 to 1,000 Hours
- 5. Request to Accept the Certification Examination of the Commission for Certification in Geriatric Pharmacy for Continuing Education Credit for Pharmacists
- 6. Emergency Preparedness for California Pharmacy Review of the Board of Pharmacy's Proposed Policy for Responding to Declared Emergencies
- 7. Information: National Patient Identifier
- 8. Competency Committee Report

Adjournment 12:30 p.m.

Memorandum

To: Licensing Committee

Date: November 29, 2006

From: Board of Pharmacy

Subject: Compounding by Pharmacies

Background:

In 2004, the Licensing Committee formed a Workgroup on Compounding to evaluate whether a distinction could be made between compounding by a pharmacy and manufacturing operations that are performed by a drug manufacturer. This workgroup formed in part due to a request from the Department of Health Services seeking the board's determination of when a pharmacy is compounding, and when a pharmacy has become a drug manufacturer, and thus subject to licensure by the Department of Health Services or federal Food and Drug Administration.

This workgroup was comprised of staff from the board, from the Department of Health Services, compounding pharmacies, pharmacy associations and others. Over the course of 2004, the group met quarterly. However, the group was unable to develop standards to distinguish when a pharmacy has crossed from compounding into manufacturing, and thus would be subject to licensure as a manufacturer. Instead, a legislative proposal and draft regulations were developed to establish standards for pharmacies that compound medication, leaving to the Department of Health Services or FDA the determination of when a pharmacy is manufacturing.

In 2005, the board sponsored the proposed statutory provisions in legislation introduced as AB 595 (Negrete-McLeod). In August 2005, AB 595 was on the floor of the Senate when opposition from the Department of Health Services was formally announced. During 2006, the board and interested stakeholders worked to remove the Department of Health Services' opposition, but we were never successful. The Department of Health Services remained opposed to various provisions, but primarily the provisions that would have allowed a pharmacy to contract with another pharmacy to compound medication for the first pharmacy. Amendments desired by Health Services would have required a separate pharmacy license and annual inspections for pharmacies that compound medication for other pharmacies.

And at the very end of the 2006 legislative session, after months of effort to remove or reduce DHS' opposition, amendments to AB 595 appeared in print that were aimed at reducing DHS' opposition. However, Kaiser, CPhA and

Grandpa's Pharmacy came out in opposition to these amendments. The board then dropped the bill.

Proposed Regulations

Staff is now recommending that the board move forward with the regulation language that was developed in 2004 for pharmacies that compound. These requirements can be adopted without the statutory provisions being enacted, and will establish standards for pharmacies that do compound, providing patient protections when they receive medication compounded by a pharmacy.

What is missing from the regulations and the regulatory scheme that was initially envisioned by the board is the authority for one pharmacy to compound medication for another pharmacy. This is currently allowed by Business and Professions Code section 4123 only for parenteral products.

If the committee recommends to the board that the board promulgate the proposed regulations, and the board agrees, it will require approximately one year for the required notice periods and administration review to put the regulations in place (about January 2008).

A copy of the proposed regulations follows.

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

(a) "Reasonable quantity" means that quantity of an unapproved drug which:

- (1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and
- (2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and
- (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.
- (b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.
- (c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

§1716.2. Record Requirements—Compounding for Future Furnishing.

(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

(1) The date of preparation.

- (2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.
- (3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (4) The signature or initials of the pharmacist performing the compounding.
- (5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.
- (6) The name(s) of the manufacturer(s) of the raw materials.
- (7) The quantity in units of finished products or grams of raw materials.
- (8) The package size and the number of units prepared.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.

Article 4.5 General Compounding

§1735. Definitions

- (a) "Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription:
 - (1) Altering the dosage form or delivery system of a drug
 - (2) Altering the strength of a drug
 - (3) Combining components or active ingredients
 - (4) Preparing a drug product from bulk chemicals

Compounding does not include the reconstitution of a drug pursuant to the manufacturer's direction for oral, rectal o topical administration.

(b)"Integrity" means the drug will retain its effectiveness until the beyond use date noted on the label.

- (c) "Quality" means the drug is free of any contaminants and only contains those active ingredients indicated on the label.
- (d) "Strength" means the amount of active ingredient in each unit of the drug.
- (e) As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:
 - (1) "Reasonable quantity" means that quantity of an unapproved drug which:
 - (A) is sufficient for that prescriber's office use; and
 - (B) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and
 - (C) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for strength, quality and integrity of the compounded medication.
 - (2) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

<u>Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, and 4052, Business and Professions Code.</u>

§1735.1. Requirements

- (a) Prior to compounding a drug, the dispensing pharmacist shall establish a professional relationship with the prescriber and patient.
- (b) A drug may not be compounded without a written master formula record that includes at least the following elements:
 - (1) Active ingredients to be used.
 - (2) Inactive ingredients to be used.
 - (3) Process and/or procedure used to prepare the drug.
 - (4) Quality reviews required at each step in preparation of the drug.
 - (5) Post compounding process or procedures required, if any.
 - (6) Beyond use dating requirements.
- (c) The pharmacist shall be responsible for assuring that the compounded drug retains its strength, quality, and integrity until dispensed.
- (d) All chemicals, drug products, and components must be used and stored according to compendial and other applicable requirements to maintain their strength, quality and integrity.

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¹ Moved from 1716.1

- (e) The beyond use date of the finished product must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies of drugs using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (f) A pharmacy may contract with another pharmacy to compound drug products, pursuant to a prescription, for delivery to another pharmacy. The compounded product must be labeled with the name of the pharmacy that compounded the drug and the information required by Business and Professions Code Section 4076.
- (g) Pharmacists who compound drugs, or supervise the compounding of drugs, shall be responsible for ensuring that the compounded drug has been prepared, labeled, stored, and delivered properly.
- (h) Prior to allowing any drug to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form XXXXX). The self assessment shall subsequently be performed before July 1 of each year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4052, and 4076, Business and Professions Code.

§1735.2. Records

- (a) For each compounded drug a record shall be made that includes at least the following elements:
 - (1) The information required of a master formula record.
 - (2) The date the drug was compounded.
 - (3) The identity of the pharmacy personnel who compounded the drug.
 - (4) The identity of the pharmacist reviewing the final product.
 - (5) The quantity of each component used compounding a drug.
 - (6) The supplier and lot number of each component.
 - (7) The equipment used compounding a drug.
 - (8) The internal reference (lot) number.
 - (9) The expiration date of the final drug.
 - (10) The quantity or amount of drug product compounded.
- (b) Pharmacies must maintain records of the acquisition, storage, and proper destruction of chemicals, drug products, and components used in compounding.
- (c) The chemicals, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall maintain certificates of purity or analysis for components, chemicals, or drug products used in compounding. Certificates of purity or analysis are not required for drugs used in compounding that are approved by the Food and Drug Administration.
- (d) Pharmacies must prepare, maintain, and retain all records required by this article in the pharmacy in a readily retrievable form for a period of three years from the date the record was created.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005 Business and Professions Code.

§1735.3. Labeling

- (a) In addition to labeling information required under Business and Professions Code Section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active component(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drugs compounded into unit-dose containers shall be labeled with the name of the active component, concentration or strength, volume or weight, and an expiration date.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4076, Business and Professions Code.

§1735.4. Policies and Procedures

- (a) Pharmacies must maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures for the pharmacy.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge.
- (c) Provisions to notify the staff assigned compounding duties of any changes in the policy and procedure manual must also be included.
- (d) The policy and procedure manual shall include written documentation of a plan for the recall of dispensed compounded products where subsequent verification demonstrates the potential for adverse effects with continued use of the compounded drug.
- (e) Written processes used to maintain, store, calibrate, clean/disinfect equipment used in compounding drug shall be contained in the policy and procedure manual and shall be incorporated as part of the staff training and competency evaluation process.
- (f) The pharmacist-in-charge shall establish policies and procedures to ensure that compounded drugs have the strength indicated by the label.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4113, Business and Professions Code.

§1735.5. Facilities and Equipment

- (a) Pharmacies shall provide written documentation of facilities and equipment necessary for the safe and accurate compounding of a drug, to also include, where applicable, certification of the facility/equipment.
- (b) Equipment shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Equipment used in compounding drug products shall be calibrated prior to use to ensure accuracy. Documentation of calibration shall be recorded in writing.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.6. Training of Staff, Patient and Caregiver

- (a) Pharmacies shall maintain written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding.
- (b) The training of pharmacy personnel shall be documented and retained as part of an ongoing competency evaluation process for pharmacy personnel involved in compounding.
- (c) Pharmacy personnel assigned compounding duties shall demonstrate knowledge about the processes and procedures used to compound drug drugs prior to compounding any drug.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.7. Quality Assurance

- (a) Pharmacies shall provide written documentation of the development of and adherence to a quality assurance plan.
- (b) The quality assurance plan shall include verification, monitoring, and review of the adequacy of the compounding process and shall include documentation of that review by the assigned personnel to demonstrate the compounded drug meets the specified criteria of strength and quality.
- (c) As part of the quality assurance plan, all qualitative/quantitative analysis reports for compounded drug drugs shall be retained and collated with the compounding record and master formula.
- (d) The quality assurance plan shall also include a written process that describes and documents the action taken when a compounded drug fails to meet the minimum standards for quality, strength and integrity.

<u>Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.</u>

Date: November 29, 2006

Memorandum

To:

Licensing Committee

From:

Board of Pharmacy

Subject: Exam for the Certification of Pharmacy Technicians

UPDATE:

In California, individuals may become qualified for registration as pharmacy technicians by one of four means:

1. Possessing an associate's degree in pharmacy technology.

- 2. Completing a course of training specified by the board in regulations (accredited by ASHP, provided by the armed forces, or at least 240 hours of instruction covering specific topics).
- 3. Graduating from a school of pharmacy recognized by the board.
- 4. Being certified by the Pharmacy Technician Certification Board.

In September the Licensing Committee began a discussion regarding another pharmacy technician examination, the Exam for the Certification of Pharmacy Technicians (ExCPT). This exam has been developed by the Institute for the Certification of Pharmacy Technicians.

This examination is accepted by Connecticut, New Jersey, Minnesota, Oregon and Virginia as a qualifying route for registration for pharmacy technicians. According to material provided by the institute, the exam is a computer-based exam, which is administered in 700 locations nationwide. The National Community Pharmacists Association and the National Association of Chain Drug stores support use of the exam.

The committee requested staff to initiate a review of the ExCPT, and whether the examination is job related and has been validated as required by California Business and Professions Code section 139.

To use the ExCPT exam as a qualifying method for pharmacy technician licensure, the either a statutory or regulation amendment needs to be adopted. The board should not proceed until this review is completed.

Within the Department of Consumer Affairs, is the Office of Examination Resources. This office provides examination and psychometric services to professional and vocational licensing boards in the department. At the current time, this office is undergoing recruitment for a chief. Until such time as a new chief is hired, the board probably should not initiate a review of the ExCPT

examination using this office.

The board could also contract for an expert to conduct this review, or require the vendor of the ExCPT to use a board-selected designated expert to conduct the review with the results going to the board.

The board has received comments from those who support the continued sole use of the PTCB examination, that the new ExCPT exam must be psychometrically sound and assessed. I am attaching a letter received from the ASHP after our October Board Meeting where the ExCPT exam was on the agenda.

At this meeting, the committee is being updated on the status of this project.



Health-System Pharmacists®

American Society of

7272 Wisconsin Avenue Bethesda, Maryland 20814 301-657-3000 Fax: 301-664-8892 www.ashp.org

October 24, 2006

Ms. Virginia Herold California Board of Pharmacy 1625 N. Market Blvd., Suite N219 Sacramento, CA 95834

Re: Licensing Committee-Request to Add the Exam for the Certification of Pharmacy Technicians Developed by the Institute for the Advancement of Community Pharmacy Technicians

Dear Ms. Herold:

On behalf of the American Society of Health-System Pharmacists, I am writing to express our interest in the Board's recent discussions regarding pharmacy technician education and training.

ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, ambulatory care clinics, long-term care facilities, home care, and other components of health care systems. Over the last twenty years ASHP has been accrediting pharmacy technician training programs and currently there are over ninety programs across the United States accredited by ASHP.

ASHP wishes to express our concerns with the potential inclusion of the alternative exam by, the Institute for the Certification of Pharmacy Technicians (ICPT). ASHP has opposed this exam in several states (see attached), based on policy adopted by our Board of Directors and House of Delegates. ASHP supports, "...mandatory certification by the Pharmacy Technician Certification Board (or another comparable nationally validated, psychometrically sound certification program) approved by the state board of pharmacy". ASHP strongly encourages the California Board of Pharmacy to carefully evaluate any exam it approves as an alternative to PTCB, which has been recognized as the national standard, and has been endorsed by the National Association of State Boards of Pharmacy. ASHP has made efforts to review the information provided by ICPT, and based on information that has been provided to our organization, we do not feel that it meets the standards set forth in ASHP policy.

Based on our analysis, ASHP has encouraged PTCB to submit its examination to the National Commission for Certifying Agencies (NCCA). NCCA is the accrediting body for the National Organization for Competency Assurance (NOCA), which is the national leader in setting quality standards for credentialing organizations. NCCA uses a peer review process to: establish accreditation standards; evaluate compliance with the standards; recognize organizations/programs which demonstrate compliance; and serve as a resource on quality certification. 1 NCCA's Standards exceed the requirements set forth by the American Psychological Association and the U.S. Equal Employment Opportunity Commission. Since ICPT has suggested that its alternative exam meets the standards set forth by the American Psychological

Association, we therefore urge the Board to request that ICPT submit its exam to NCCA prior to review and approval by the California. PTCB has also submitted its exam to NCCA for an independent review and accreditation. We believe that without an independent review the Board should consider any alternative exam to the already established national standard met by PTCB. That standard is based on its inclusion in the majority of states, its recognition by major employers in all settings (hospital, major chains etc) and its recognition by the National Association of State Boards of Pharmacy.

ASHP urges the Board to conduct a comprehensive review, requesting full and complete disclosure of relevant information in order to evaluate the ICPT certification process. The National Association of State Boards of Pharmacy (NABP) issued a memorandum to its member Boards earlier this year (see attached) which provided guidance evaluating proposals for examinations that test pharmacy technicians. ASHP strongly encourages the Board to carefully review the recommendations made by NABP and other stakeholders who have expressed concerns with this exam before it is approved in your state.

If you have any questions or comments please do not hesitate to contact Maria D. Spencer, Director of State Government Affairs at 301.664.8687 or mspencer@ashp.org.

Sincerely,

Byan M. Hay

Brian M. Meyer, M.B.A.

Director, Government Affairs Division

cc: Brian Hodgkins, Pharm.D, President, California Society of Health System Pharmacists Maria Serpa, Pharm.D, Government Affairs Committee, California Society of Health System Pharmacists

Robert Batman, Pharm.D., Chair, Government Affairs Committee, California of Health System Pharmacists

Enclosures

Memorandum

To: Licensing Committee Date: November 27, 2006

From: Board of Pharmacy

Subject: Pharmacist Intern Competencies

The board was recently advised about a review of the intern experience component of pharmacy education that is being initiated by California's schools of pharmacy. This group will examine both the required and elective components of ACPE approved intern experience at both the basic (IPPE) and advanced (APPE) levels. The project will be called the California Pharmacy IPPE/OSCE Initiative. The goal is to develop an alternative component to assessing intern experience.

The California pharmacy schools are collaborating on this new initiative to determine and assess the competencies that students should achieve by the end of their introductory pharmacy practice experiences (IPPEs) prior to starting their advanced pharmacy practice experiences (APPEs). This initiative is in response to new ACPE accreditation standards that spell out how much time students must spend in IPPEs and APPEs rather than what they should learn (outcomes).

During the first phase of the project, the committee will determine the competencies that students should achieve. One item they will use is the old Board of Pharmacy Intern Affidavits as a starting point. The second phase involves developing a reliable and valid performance-based exam (i.e., objective structured clinical exam, OSCE) to assess student achievement of these competencies.

At this Licensing Committee Meeting, Barbara Sauer, PharmD, of UCSF's School of Pharmacy will provide information about what this group will evaluate and hopes to accomplish. Details about the initiative are provided in this tab section.

President Powers has appointed Board Member Susan Ravnan as the board's representative to this group.

One concern of the group is that requiring a specific duration of experience (i.e., 1,500 intern experience hours) but without specifying the components to be gained from the experience is not beneficial.

The goals of the initiative are to:

- 1. Reach consensus on the basic foundational competencies that all pharmacy students in California should master during basic intern experiences.
- 2. Train faculty members from each pharmacy school in California how to develop and administer an OSCE-based assessment.
- 3. Develop a validated and standardized OSCE-based examination to assess achievement of the basic competencies
- 4. Develop a mechanism to assure replenishment of the OSCEs and exam security

in the future

5. Petition ACPE to accept an OSCE-based assessment for basic experience as evidence of compliance with specific ACPE standards.

The timeline aims for incorporation of the standards during academic year 2007-08.

California Pharmacy IPPE/OSCE Initiative

The experiential component of the pharmacy curriculum provides a continuum of required and elective practice experiences that progress from basic (IPPEs) to more advanced (APPEs) activities under the supervision of qualified preceptors. Together, IPPEs and APPEs are designed to provide students with multiple opportunities to perform patient-centered care in a variety of real practice settings.

Background Situation

Recently, ACPE adopted new accreditation standards and guidelines (Standards 2007).

- Requirements for practice experiences are based upon amount of time spent:
 - o IPPEs must be 5% of length of the curriculum; and
 - o APPEs must be 25% of the length of the curriculum.
- Appendix C provides guidance on types of experiences appropriate for IPPEs and APPEs.
- The desired curricular outcomes (professional competencies) as a whole (i.e., for graduates) are described, but there is no delineation between IPPEs and APPEs in terms of the competencies that should be mastered in IPPEs prior to progressing to APPEs.

The California State Board of Pharmacy requires candidates for licensure to submit proof of 1500 hours of internship.

- Minimum of 900 hours must be completed in community or hospital practice settings.
- Up to 600 hours may be granted for other experiences substantially related to practice of pharmacy, which are generally provided by the schools for practice-related educational experiences.
- Students may apply for Intern licenses once registered in a school of pharmacy.

In the past, the State Board required candidates to submit two intern experience affidavits, one for community practice and one for institutional practice experiences. These affidavits listed specific practice objectives (competencies) that had to be signed off by licensed pharmacists. Currently, candidates for licensure only submit a 2-sentence affidavit, which they sign, stating that they have met the required internship requirements and have experience in both community and institutional pharmacy settings.

Relative to many other states, California schools of pharmacy admit a high percentage of educationally mature students. It is not uncommon for 90-95% or more of the entering classes at California schools to have earned a bachelors degree or higher. Many students have worked or volunteered in pharmacies prior to entering pharmacy school, with some having extensive experience as pharmacy technicians. While in school, the majority of California pharmacy students work as pharmacy interns and participate in professional organizations and co-curricular activities (e.g., health fairs, disease screenings, immunizations, smoking cessation programs, Medicare Part D outreach, indigent care clinics).

The Problems

The emphasis on the duration of experiences rather than the curricular outcomes resulting from them is problematic for many reasons. First, established schools are faced with adding course work to their (already packed) existing curricular, with no assurance that doing so would improve the quality of education for their graduates. If more time is to be spent in one aspect of the

curriculum, something will need to be removed elsewhere to avoid prolonging the time to graduation. This is especially problematic in California, where a high percentage of students already spend eight or more years in college prior to entering the profession.

Secondly, although individual schools have goals and learning objectives for IPPEs, there is no consistency or standard across schools regarding the types of practice activities offered or what students should learn or master. There is even less direction regarding appropriate activities for the State Board internship, which often results in pharmacy interns remaining in positions where they perform repetitive tasks at the expense of gaining experience with a broader array of more advanced professional responsibilities.

A third problem is that the new IPPE requirement does not provide sufficient flexibility in how schools will meet the standard. Students with extensive pharmacy technician experience should not be forced to repeat experiences that are of little educational value to them. Students working as interns in retail and hospital pharmacies may be able to achieve some of the foundational competencies through employment. Schools may wish to capture student participation in co-curricular activities such as disease screenings, Medicare outreach, and providing services to patients of indigent care clinics, which contribute to the development of professionalism and leadership skills among students. These types of activities promote a positive image of the profession and increase the public's awareness of the contributions that pharmacists make to improving health care outcomes.

Goals

The goals of this initiative are to:

- 1) Reach consensus on the basic foundational competencies that all pharmacy students in California should master during IPPEs (June 2007).
- 2) Train faculty members from each pharmacy school in California how to develop and administer an OSCE-based assessment (September 2007).
- 3) Develop a validated and standardized OSCE-based examination to assess achievement of the IPPE competencies (academic year 2007-08).
- 4) Develop a mechanism to assure replenishment of the OSCEs and exam security in the future (academic year 2007-08).
- 5) Petition ACPE to accept an OSCE-based assessment for IPPEs as evidence of compliance with Standards 10 and 14 in California (academic year 2007-08).

Proposal

- 1) The IPPE/OSCE Committee will identify and agree on the competencies that should be achieved by the end of IPPEs.
 - a) Composition: 2-3 representatives from each school
 - b) Invited participants: representatives from the state Board of Pharmacy, CPhA, CSHP, and other appropriate entities
 - c) Meetings:
 - a. January 23, 2007, 10:00 am 3:00 pm, San Francisco (UCSF)
 - b. February 27, 2007, 10:00 am 3:00 pm, Los Angeles (USC)
 - c. March 27, 2007, 10:00 am 3:00 pm, San Francisco (UCSF)
 - d) Decisions: Each participating school would have one vote when making decisions.

- e) Background materials: The State Board of Pharmacy's community and institutional internship experience affidavits, NAPLEX Blueprint 2005
- 2) The committee will sponsor two 1.5 day statewide OSCE conferences to train faculty teams from each school on how to develop and administer OSCEs. The goal is to produce a bank of 40+ OSCE stations for the IPPE assessment. Zubin Austin (University of Toronto) has agreed to lead the conferences.
 - a) First conference (San Francisco, June 5-6, 2007). Topics will include an overview of OSCEs (primer), developing the exam blueprint, defining stations, and developing the initial cases.
 - b) Interlude: faculty teams will develop additional cases/stations (5-7 per school).
 - c) Second conference (San Diego, week of August 20, 2007). Topics will include review and validation of the additional cases/stations, setting standards, determining station set up and training requirements, determining data analysis (cut scores), determining security procedures and establishing a mechanism to replenish cases in the future.
- 3) The committee will pursue external funding to offset the expenses associated with committee meetings and the OSCE conference(s). If not successful, schools will share the costs equally.
- 4) Schools will select 7-9 OSCE cases/stations from the database for each assessment, based upon individual needs and preferences. Exams may be offered at different times, but all schools agree to follow the established procedures and security measures.
- 5) Appoint representative(s) from each school to meet on an annual basis to share experiences with the exams and generate new cases/stations to replenish the database.

Memorandum

To: Licensing Committee Date: November 27, 2006

From: Board of Pharmacy

Subject: Pharmacist Intern Hours Requirements

Under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensing examinations.

More specifically, board regulations specify that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. The remaining 600 hours can be granted for experience under the supervision of a pharmacist substantially related to the practice of pharmacy, but not specifically within a pharmacy. California pharmacy students typically earn the 600 "discretionary" hours for school-required experiential training (clinical clerkship).

At the March 2006 Licensing Committee Meeting, pharmacy students from USC and other pharmacy schools presented a proposal requesting that the Board of Pharmacy amend its requirements to redirect from the 900 hours currently required to be earned inside a pharmacy, an additional 400 hours (for a total of 1,000 hours of the 1,500 hours required) that an intern can earn for pharmacy-related experience (under the supervision of a pharmacist) outside a pharmacy. This initial request and summary from the March Meeting is attached.

So should the regulation be modified as proposed by the students, an intern would need to earn a minimum of 500 hours in a pharmacy and a maximum of 1,000 hours substantially related to the practice of pharmacy under the supervision of a pharmacy, but not necessarily within a pharmacy.

According to the students, opportunities for pharmacists have expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours for this experience. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth years in both community and hospital pharmacy. In the fourth year, pharmacy experience is more clinical. A large percentage of pharmacy students would still earn the majority of the intern hours in a pharmacy. This option would be for those students that show proficiencies in the pharmacy settings and would like to expand their experience in other areas.

At the March Licensing Committee Meeting, the National Oncology Alliance, Inc., (NOA)

spoke in support of the proposal and gave a presentation on opportunities for interns outside a licensed pharmacy and under the supervision of a pharmacist. For example, the intern would assist the NOA clinical team to prepare clinical summaries of articles in the medical literature, collect data about the status of drug approvals as they apply to NOA treatment guidelines and assist with the development and yearly revision of NOA treatment guidelines. NOA advocated that patient care activities meet the Accreditation Council for Pharmacy Education (ACPE) criteria, and content outline of the California Pharmacist Jurisprudence Examination.

Dean Koda Kimble for the UCSF School of Pharmacy submitted a latter expressing concern over the proposal and the board not to amend the regulation (attached).

The Licensing Committee did not make a recommendation on this proposal the committee discussed the board's responsibility to protect the public. However, it is important that an intern pharmacist is capable of performing the core competencies of pharmacy practice. An intern has the authority to perform all the duties of a pharmacist under the supervision of a pharmacist. There was concern expressed that a minimum of 500 hours of intern experience in a pharmacy is not sufficient to assure adequate public safety and the experience necessary to perform the duties of a pharmacist. It was not clear how experience with a pharmaceutical manufacturer, in regulatory affairs or association management would provide an intern with the skills critical to the practice of pharmacy. The core functions of pharmacy include patient consultation and quality assurance, key skill areas and knowledge that an intern can only gain in real life experience and daily practice in a pharmacy.

No further action on this item has taken place since the March meeting.

At This (December 2006) Licensing Committee Meeting:

At this meeting, the students will attend and bring this issue before the committee.

I am enclosing materials from the March 2006 meeting.

§1728. Requirements for Examination.

- (a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
- (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
- (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
- (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
- (C) Experience in both community pharmacy and institutional pharmacy practice settings.
- (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.
- (2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.
- (3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.
- (4) A signed copy of the examination security acknowledgment.
- (b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from
- each state in which the applicant holds or held a pharmacist license prior to being authorized by the boar to take the examinations.
- (c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Authority cited: Sections 851, and 4005, Business and Professions Code. Reference: Sections 144, 851, and 4200, Business and Professions Code.

State of California

Memorandum

To:

Licensing Committee

Date: March 9, 2006

From:

Patricia Harris

Executive Officer

Subject: Request to increase the number of intern hours that

can be earned outside of a pharmacy

At the February meeting, the board was provided with a proposal from a group of pharmacy students representing various schools of pharmacy requesting an increase in the number of intern hours that could be earned outside a pharmacy. Since the proposal was not on the agenda, the board could not take action.

The proposal is now being provided to this committee for consideration. The proposal requests that the board allocate up to 400 hours that an intern can earn for pharmacy-related experience (under the supervision of a pharmacist) outside a pharmacy. The proposal is attached.

Under current law, an intern must earn a minimum of 900 hours of pharmacy experience under the supervision of a pharmacist in a pharmacy. The board has the discretion to grant a maximum of 600 hours for other experience substantially related to the practice of pharmacy. California pharmacy students earn the 600 hours for school required experiential training (clinical clerkship).

Therefore as proposed, an intern would only need to earn a minimum of 500 hours in a pharmacy and could earn a maximum of 1,000 hours of experience substantially related to the practice of pharmacy under the supervision of a pharmacist.

16 CCR § 1728 states in part:

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a

pharmacy. (B) A maximum of 600 hours of pharmacy practice experience may be granted at the

discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.



RESOLUTION FOR CONSIDERATION BY THE CALIFORNIA STATE BOARD OF PHARMACY

WHEREAS the scope of practice opportunities in the profession of pharmacy has expanded beyond the traditional areas of community and institutional pharmacy, and

WHEREAS the increased scope of pharmacy based opportunities exist for pharmacy school graduates in such areas as the pharmaceutical industry, managed care; regulatory affairs, and other pharmacy-related areas to yet be defined, and

WHEREAS the present existing laws place requirements on both the experience expectations and the quantity of time required of students enrolled in California Schools of Pharmacy in order for them to satisfy both the board exam and licensure standards as stated in the following California statutes and regulations:

CA Bus. & Prof. Code, Sec. 4200(a)(5): "The board may license as a pharmacist any applicant who meets the following requirements... Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Sec. 4209."

CA Bus. & Prof. Code, Sec. 4209(a)(1)(2): An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination. This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

<u>Title 16, CA Code of Regulations, Sec. 1728(a)</u>: ...Applicants shall submit to the board the following: Proof of 1,500 hours of pharmacy practice experience that meets the following requirements:

- (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
- (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
- (C) Experience in both community pharmacy and institutional pharmacy practice settings.
- (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education. And

WHEREAS while the American Council on Pharmaceutical Education (ACPE) does support that the Schools of Pharmacy engage students during the experiential portions of its academic program in various patient care settings, it also encourages other extended boundaries of learning during the experiential portion of the academic program. Under Standard No. 14 (Curricular Core: Pharmacy Practice Experiences), Guideline 14.1 it states the following:

"The scope, intensity, and duration of all of the pharmacy practice experiences should afford students the opportunity to develop skills consistent with expected professional competencies and outcomes. The pharmacy practice experiences should ensure that every student has multiple opportunities to perform pharmaceutical/patient-centered care activities in a variety of settings (including acute care, long-term care, home care, community, ambulatory, administrative)..." And

WHEREAS all students who undergo the pharmacy curriculum at the University of Southern California School of Pharmacy have multiple pharmacy-related experiences that might include managed care and industrial pharmacy settings that count toward their 600 required hours of experiential training, those areas of experiences that are more directly patient based are assessed by the use of competency criteria once established by the California State Board of Pharmacy for both community and institutional practices. Students, based upon those competency standards, must achieve a passing mark on each competency stated in order to pass that practice-based course. In passing the practice-based courses, the School is essentially stating that that student is competent to sit for the board examination and practice as a competent pharmacist once the student has passed the board exam, and

WHEREAS, at this point in time, only a small contingent of those graduating seek positions in the pharmaceutical and managed care industries (perhaps less than 10% of the graduating students), their role in being versed in good patient care principles and standards of care is not diminished based upon the demands of these entities both directly and indirectly being responsible for the assurance that the highest of standards be undertaken that all services and/or products rendered or produced shall be of the highest quality to the recipients of those services and/or products, and

WHEREAS it has not been established, as to at least the knowledge of those who have created this resolution and recommendation, that 1500 hours of patient-related contact is either over or under abundant in assuring that a pharmacist will be minimally competent to practice patient-care pharmacy upon being licensed,

THEREFORE LET IT BE RESOLVED/RECOMMENDED that the California State Board of Pharmacy (Board) recognize that intern experiences in the areas of pharmaceutical industry and managed care can have both a direct and indirect impact on patient care. In so recognizing, be it resolved and recommended that the Board allocate up to 400 hours from the 900 hour remainder that does not include the 600 hours allocated to pharmacy school experiential programming for the purposes of gaining experience in new pharmacy practice related areas such as and not limited to industrial pharmacy and managed care.

THEREFORE LET IT FURTHER BE RESOLVED/RECOMMENDED as a modification of *Title 16*, *Calif. Code of Regulations*, *Section 1718[a][1][A-D]* that presently reads as follows:

- (a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
 - 1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
 - (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
 - (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
 - (C) Experience in both community pharmacy and institutional pharmacy practice settings.
 - (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

THAT THE MODIFICATION OF <u>Title 16</u>, <u>Calif. Code of Regulations</u>, <u>Section 1718[a][1][A-D]</u> BE AS FOLLOWS:

- (a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
 - Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
 - (A) A minimum of 500 hours of pharmacy practice experience must be obtained in community and institutional pharmacy practice settings..
 - (B) A maximum of 1000 hours of pharmacy-related practice experience must be obtained under the supervision of a pharmacist. This 1000 hours may involve, but is not limited to the attainment of pharmacy-related practice experience in a community pharmacy, an institutional pharmacy setting, a managed care organization, and a pharmaceutical industrial setting. The 1000 hours shall include the current 600 hours that is granted for pharmacy school experiential programming, and the additional 400 hours for other pharmacist supervised pharmacy-related experiences.
 - (C) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

University of California San Francisco



School of Pharmacy Office of the Dean

Mary Anne Koda-Kimble, PharmD Professor and Dean TJ Long Chair in Chain Pharmncy Practice 521 Parnassus Avenue Box 0622, Roem C-156 San Francisco, CA 94143 to: 415/476-8010 tax: 415/476-6632 kodakimblem@pharmscy.ucsf.edu

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April 18, 2006

Ms. Patricia Harris, Executive Officer State Board of Pharmacy 1625 North Market Blvd., N219 Sacramento, CA 95834

Dear Patty,

I am writing regarding the agenda item titled, "Request to Modify Intern Hours Earned for Pharmacy-Related Experience," a proposal to amend 16 CCR 1728. The UCSF School of Pharmacy opposes this proposal and appreciates the opportunity to convey our rationale.

I am familiar with the genesis of this proposal, since it is not the first time intern hours have been open to debate. In fact, I strongly supported a change in the regulation, which allowed students to receive credit for up to 600 hours of clinical clerkship experiences that were "substantially related to the practice of pharmacy," several decades ago. While I strongly encourage and promote student leadership initiatives and applaud the activism of our student groups, I differ with the views of students on this issue.

Currently, the Board of Pharmacy requires a total of 1500 Intern hours. Of these, 600 can be in a setting that is "substantially related to the practice of pharmacy"; the remaining 900 hours must be in a pharmacy under the supervision of a pharmacist. One of the stated reasons for the proposal (to allow up to 1000 hours of experience that is substantially related to the practice of pharmacy) is that it would provide students the opportunity to earn intern hours for new and innovative experiences that are not in a pharmacy. It has also been suggested that students do not pursue experiences in contemporary practices outside of licensed pharmacies because these do not qualify for intern hours required for licensure. We believe that the current regulation provides ample opportunity for students to pursue innovative experiences without jeopardizing their ability to complete the Board's requirement before graduation. We also believe that practice experience in a licensed pharmacy is absolutely essential to the development of a future pharmacist.

The UCSF School of Pharmacy curriculum currently includes *more than 1000 hours* of advanced pharmacy practice experience (clerkship) that would meet the Board's criteria for hours that are "substantially related to the practice of pharmacy." We assume the other California Schools of Pharmacy also meet or exceed this 1000 hour threshold. Therefore, the proposed change to 1000 intern hours "substantially related to the practice of pharmacy" would be entirely covered by the School's advanced pharmacy practice experiences. Consequently, the majority of students would simply be required to spend 400 fewer intern hours in a licensed pharmacy if this change is approved.

For more than 40 years the UCSF School of Pharmacy has designed and refined the educational experience it requires of students in the context of the Board of Pharmacy's requirement of 900 hours of practice experience in a pharmacy. This relationship has allowed the School to be creative in the types of practice experiences that are offered to our students since we know that an essential foundation for practice is provided through internship experiences in a pharmacy. A substantial change in the number of intern hours that are required in a licensed pharmacy (both institutional and community) will significantly disrupt the balance between the School's curricular experiences and the core skills and competencies students develop through their work as interns in licensed pharmacies. Our curriculum is predicated on this balance of experience and we believe the proposed change would not insure that our graduates have the core pharmacy skills and experiences we believe the public expects.

The UCSF School of Pharmacy has long embraced innovation in the profession and our new curricular pathways in *Pharmaceutical Health Policy & Management* and *Pharmaceutical Sciences* support our commitment to engaging students in new and expanding areas of practice. We also have mechanisms that allow individual students to substitute innovative practice experiences for some of their elective advanced pharmacy practice experiences. This process is evaluated by a faculty committee and allows for additional practice activities that are individualized, creative and innovative - though not yet mainstream.

Finally, the current requirement for 900 intern hours in a pharmacy under the supervision of a pharmacist can be met by one summer's full-time internship coupled with part time internship work during the student's academic year(s). We believe this allows most students at least one summer to explore outside professional activities that are professionally rewarding but do not meet the Schools' or Board's criteria for earning credit towards their academic degree and licensure.

The students' desire to expand the areas of practice experience and their focus on innovation — which are at the heart of this proposal — is to be commended. At the same time, we believe that the Board's requirement of 900 hours (less than one-half year) experience in a licensed pharmacy remains an essential component of the training and licensure of pharmacists who can best serve the public's needs. I also encourage the Board to once again adopt a statement of competencies to be gained from internship experiences in licensed pharmacies. Such a statement can be used to guide both students and preceptors in creating experiences that develop core competencies and skills the public deserves.

I am happy to discuss this in more detail with you and the Board.

Sincerely.

Mary Anne Mary Anne Koda-Kimble, PharmD

Professor and Dean

TJ Long Chair in Chain Practice Pharmacy



Memorandum

To:

Licensing Committee

Date: November 29, 2006

From:

Board of Pharmacy

Subject: Emergency Preparedness for California

At the October Board Meeting, the board amended and approved a general policy statement that outlines its expectations for how disaster response in California may proceed.

Over the coming months, the board will work with the Department of Health Services to provide responses to their questions. The goal of the board and the DHS is to assure that concerns can be addressed at the front end, and licensees and the public will have better knowledge of what the board will require, and be willing and comfortable volunteering to participate in emergency response.

Legislation or regulation changes may be an outcome of these discussions.

The modified disaster response policy follows on the next page.

Disaster Response Policy Statement

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. Skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at www.medicalvolunteer.ca.gov (California) and www.medicalvolunteer.ca.gov (California) and www.medicalreservecorps.gov (federal). The board also continues to be actively involved in such planning efforts, at every level.

The board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected. The board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

¹ Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

Furthermore, during a declared disaster or emergency affecting residents of California, the board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California.² The board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California. Finally, the board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

² See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states.

Date: November 27, 2006

Memorandum

To: Licensing Committee

From: Board of Pharmacy

Subject: National Provider Identifier (NPI)

FOR INFORMATION:

One component of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) required that the Health and Human Services Agency adopt a unique health identifier for health care providers. On January 23, 2004, the government published the final rule creating the National Provider Identifier (NPI) as the identifier.

All HIPAA-covered providers, whether they are individuals or companies, must obtain an NPI for use in HIPAA covered, HIPAA standard transactions (e.g., NCPDP for retail prescription drugs). This affects pharmacists and pharmacies, all of whom will need to obtain an NPI. Once issued, a provider's NPI will not change, even if a pharmacist's job or pharmacy location changes.

HIPAA-covered entities must use only the NPI to identify covered health care providers in standard transaction by May 23, 2007.

Pharmacists and pharmacies can obtain this number from CMS.

Materials regarding the NPI are contacted in this tab section.





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National Provider Identifier Standard (NPI)

Overview

What's New How to Apply Educational Resources Enumeration Reports Medicare NPI Implementation **EFT** Questions

Overview

Only 188 more days until the National Provider Identifier (NPI) compliance date! Do you have your NPI?

Transcript for 9/26/06 NPI Roundtable Now Available

The complete transcript for the 9/26/06 NPI Roundtable is now available - click on "Educational Resources" to the left of your screen to view this document.

NPI Tip

When applying for your NPI, CMS urges you to include your legacy identifiers, not only for Medicare but for all payors. If reporting a Medicaid number, include the associated State name. This information is critical for payors in the development of crosswalks to aid in the transition to the NPI.

View a letter (located in the Downloads section below) from CMS Administrator, Dr. Mark B. McClellan, announcing the start of NPI enumeration for all health care providers.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated that the Secretary of Health and Human Services adopt a standard unique health identifier for health care providers. On January 23, 2004, the Secretary published a Final Rule that adopted the National Provider Identifier (NPI) as this identifier.

All HIPAA covered healthcare providers, whether they are individuals or organizations, must obtain an NPI for use to identify themselves in HIPAA standard transactions. Once enumerated, a provider's NPI will not change. The NPI remains with the provider regardless of job or location changes.

HIPAA covered entities such as providers completing electronic transactions, healthcare clearinghouses, and large health plans, must use only the NPI to identify covered healthcare providers in standard transactions by May 23, 2007. Small health plans must use only the NPI by May 23, 2008.

Downloads

NPI Final Rule [PDF, 249KB]

Dear Provider Letter from CMS Administrator [PDF, 125KB]

Related Links Inside CMS

HIPAA - General Information

Related Links Outside CMS



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National Council Ing Prescription Drug Programs NCPDP

FAQs on NPI Enumeration

What is an NPI? (revised 7/1/06)

The National Provider Identifier (NPI) is the provider identifier, replacing the different provider identifiers pharmacies currently use including the NCPDP Provider ID number (formerly the NABP number). This identifier, which implements a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), must be used by most HIPAA covered entities, which are health plans, health care clearinghouses, and health care providers that conduct electronic transactions for which the Secretary has Health care providers include adopted a standard (i.e., standard transactions). individuals, such as physicians, dentists, and pharmacists, and organizations, such as hospitals, nursing homes, pharmacies, and group practices. The use of the number on HIPAA transactions is mandatory by May 23, 2007 for most health plans (2008 for found plans). More information can be health http://www.cms.hhs.gov/apps/npi/01_overview.asp

How do pharmacies obtain their NPI? (revised 7/1/06)

Pharmacies are able to apply for their NPI in one of three ways:

- (1) With their permission, NCPDP will submit their application in an electronic file and provide the pharmacy's NPI to them. NCPDP recommends this option as a service to the industry. This authorization process is underway and the NCPDP bulk enumeration process has begun. Go to http://www.ncpdp.org/frame_news_npi-info.htm
- (2) Pharmacies may prepare a paper application and send it to the entity that will be assigning the NPI on behalf of the Secretary (the Enumerator). A copy of the application, including the Enumerator's mailing address, is available on at http://www.cms.hhs.gov/NationalProvIdentStand/03 apply.asp#TopOfPage
 Pharmacies may also call the Enumerator for a copy. The phone number is 1-800-465-3203 or TTY 1-800-692-2326.
- (3) Pharmacies may apply through a web-based application process. The web address is the same as #2 above.

What is the NPPES? (revised 7/1/06)

NPPES is the National Plan and Provider Enumeration System. CMS and the Enumerator, Fox Systems, Inc., use this system to enumerate and maintain information on all providers who apply for an NPI or submit changed information. The NPPES does not have the capability to link a group of pharmacies together into a chain or other affiliations. In addition, it is not currently known if, how, or when CMS will disseminate NPI numbers to industry. For this reason, it is important that the industry continue to use the NCPDP Pharmacy Database, which will include a pharmacy's new NPI(s) crosswalked to their NCPDP Provider ID to avoid industry disruption in converting from the NCPDP Provider ID to the NPI.

What is an "EFI Organization"? (revised 7/1/06)



An EFI Organization (EFIO) is a term used by CMS to describe an entity that has been certified by CMS to serve as an authorizing provider's agent in submitting an electronic NPI application for the provider and to distribute the NPI to the provider(s). EFIOs may also submit changes to provider data such as address and maintain provider data in the NPPES. EFIOs are certified by CMS through their Enumerator before they are able to perform these functions. There is no other way to batch enumerate a group of pharmacies. All other NPI enumeration methods (web and paper) require individual applications, one-by-one, and require one-by-one updates.

NCPDP is a certified EFIO and recommends pharmacies obtain their NPIs by authorizing NCPDP as their EFIO. This will insure data are correct on the NPPES as well as on the NCPDP Pharmacy Database available to industry.

Do all pharmacies need an NPI?

All pharmacies that submit HIPAA covered transactions must obtain and use an NPI by May 23, 2007. NCPDP recommends all pharmacies obtain an NPI, even if HIPAA covered transactions are not used by the pharmacy.

Has CMS approved NCPDP to be an EFIO? (revised 7/1/06)

Yes. NCPDP is certified to submit records for enumeration on behalf of pharmacies with their authorization. In May, NCPDP submitted smaller files and streamlined business processes in the live environment. NCPDP has steadily increased the number of files submitted weekly as well as the size of those files. NCPDP is currently accepting updated information and authorizations from pharmacies. With the exception of new pharmacies and change of ownerships, pharmacies are enumerated in the order in which their updated information is received, allowing for CMS file size and frequency restrictions. New pharmacies and Change of Ownership situations take priority.

Why should a pharmacy use NCPDP as an EFIO to obtain NPIs? (revised 7/1/06)

NCPDP has been successfully enumerating pharmacies since 1981 during which time NCPDP has provided pharmacies with NCPDP Provider ID numbers (formerly known as NABP numbers). In addition to enumeration, NCPDP maintains the NCPDP Pharmacy Database, which is purchased by industry for many uses including claims processing, product recalls, publications, network development and health plan directories. Using NCPDP to obtain NPIs will insure pharmacy information is current on the NCPDP Pharmacy Database, result in minimal industry disruption and aid in proper claims reimbursement.

If a pharmacy is owned or are affiliated with a group of pharmacies, there is no other way of applying for NPIs other than a single web-based or paper application per pharmacy. Enumerating a large group of pharmacies can result in significant administrative burden associated with gathering, formatting, editing, validating, applying over the web (which CMS states takes 20 minutes per number) and maintaining data in NPPES.



Will NCPDP discontinue issuing NCPDP Provider (formerly NABP) ID numbers? (revised 7/1/06)

No, NCPDP will continue to issue NCPDP ID numbers, even if they are not used on a HIPAA standard transaction. NCPDP expects Workers Compensation and other programs not covered by HIPAA will continue to use NCPDP Provider ID numbers for some time into the future. It is expected that many processors will crosswalk the NPI to the NCPDP Provider ID and will continue to use the NCPDP ID for processing in the near to intermediate term. The relationship and demographic information found on the NCPDP Database files is needed more than ever by the industry. NCPDP will continue issuing NCPDP Provider ID numbers - even if the only future use is internal to NCPDP and users of our database. There are no plans to phase out the numbers.

So, NCPDP is going to continue to assign NCPDP numbers even after NPI is fully operational? If so, for how long? (revised 7/1/06)

Yes. Industry is continuing to use NCPDP ID numbers on claims until May 23, 2007 and after that date, most claims processors if not all will simply convert the NPI to the NCPDP ID before processing. NCPDP has committed to industry that there will be a one-to-one relationship between NCPDP Provider ID numbers and NPIs so that industry can easily develop crosswalks between the NPI and the NCPDP Provider ID number for information and claims processing systems. NCPDP will perform this service indefinitely.

How can NCPDP do all the work necessary for EFI submission at *no additional* cost to pharmacies?

NCPDP can do all the work required at no additional cost to pharmacies just like they do today in maintaining the NCPDP Pharmacy Database. NCPDP sells this database to the industry to recoup its pharmacy NPI enumeration costs. NCPDP, with a pharmacy's authorization and the required information on an NCPDP-developed Application Form or Excel format, will obtain pharmacy NPI(s) and maintain NPIs (i.e. maintaining the CMS National Plan and Provider Enumeration System, NPPES) for authorizing pharmacies as required by Federal Law. NCPDP agrees that all this work will be done at no additional cost to pharmacies. The only cost involved is the current cost of \$100 for enumerating new pharmacies or those that change ownership.

What are the advantages of using NCPDP as an EFIO? (revised 7/1/06)

If a pharmacy is owned or are affiliated with a group of pharmacies, there is no other way of applying for NPIs other than becoming an EFIO or applying for each pharmacy using an individual web-based or paper application. Enumerating a large group of pharmacies can result in significant administrative burden gathering, formatting, editing, validating, and maintaining data in addition to filling applications and correcting errors.

Pharmacies benefit from the various industry uses of NCPDP's Pharmacy Database information. Specifically, entities within the pharmacy industry use this pharmacy



information for affiliating pharmacies with their respective chain headquarters or networks, claims processing, direct mailings of product recalls and publications, network development, health plan directories and rebate information. NCPDP, functioning as an EFIO provides pharmacies with a single method of maintaining pharmacy information in this important industry database as well as the NPPES, which does not contain all the information needed by industry to process claims.

NCPDP's Pharmacy Database contains pharmacy NPI(s) as well as legacy NCPDP Provider ID numbers (formerly the NABP number). This provides industry with the much-needed crosswalk between the two IDs and minimizes industry disruption or errors in claims payment.

What entities other than pharmacies will NCPDP enumerate?

There are some entities or non-pharmacy dispensing sites that dispense medication under the supervision of a physician such as certain clinics, emergency rooms or dispensing physicians. NCPDP can enumerate those non-pharmacy dispensing organizations (not the physician) in addition to pharmacies.

Will NCPDP also enumerate pharmacists?

No. NCPDP is only enumerating pharmacies, non-pharmacy dispensing sites and certain DME providers. If a pharmacist **bills** for medication therapy management or other professional pharmacy services or conducts any other HIPAA standard transactions, pharmacists must obtain an individual NPI.

Will this allow my pharmacist to be paid directly for their services?

In some cases, it will be the pharmacy that is to be paid for the pharmacist's medication therapy management or professional services. In that case, the NPI of the pharmacy is the biller, (NCPDP Service Provider ID on the Telecommunication Standard Version 5.1 Claim) and the NPI of the pharmacist is the rendering provider (Pharmacy Provider Segment on the Version 5.1 Claim).

What was the purpose of the pledge pharmacies were asked to sign last year on behalf of our affiliated pharmacies? (revised 7/1/06)

The pledge NCPDP requested from organizations representing various groups of pharmacies in late 2005 was to determine industry interest in NCPDP becoming an EFIO and to help NCPDP size the level of effort NCPDP would have enumerating pharmacies. The pledge also insured organizations received regular communication regarding the status of the enumeration. Now that NCPDP is an authorized EFIO, the pledge has no importance. It is important now that pharmacies *authorize NCPDP* to be their EFIO. This can be done by updating pharmacy data with NCPDP using the NCPDP Application/Update Form, Checking the box and signing Section 11 of the Application. The Form can be found at http://www.ncpdp.org/frame_news_npi-info.htm. If the organization is a larger chain, an Excel Template is available and an Authorization



Letter. This information is also available at http://www.ncpdp.org/frame_news_npi-info.htm.

What do pharmacies do to authorize NCPDP to be their EFIO in obtaining NPIs? (revised 7/1/06)

NCPDP has emailed all those that have submitted pledges and asked for authorization. There is also a link to the NCPDP website where individual pharmacies can download a form to fill out the necessary information and authorize NCPDP. The link is http://www.ncpdp.org/frame_news_npi-info.htm. The form can be faxed or mailed to NCPDP.

If an organization owns many pharmacies, an Excel file template and Chain Authorization Letter is available at the same site.

Our chain has more than one relationship or chain code. Do we need to fill out one Excel Template for each chain code? (revised 7/1/06)

Yes. NCPDP needs one spreadsheet for each chain code. This is because NCPDP sets permission flags for authorization to enumerate based on chain codes and NCPDP submits batches or files to NPPES for chains based on chain code.

What are the pharmacy's responsibilities in order for NCPDP to enumerate? (revised 7/1/06)

Federal Law requires the information sent to NPPES to enumerate a pharmacy be correct. The pharmacy's responsibility is to verify NCPDP has the correct information on the pharmacy. The best way to do this is to go to http://www.ncpdp.org/frame_news_npi-info.htm and send NCPDP the updated Application and indicate the pharmacy is updating pharmacy information and authorizing NCPDP to be an EFIO.

NCPDP is updating information on the NCPDP Pharmacy Database based upon these Applications and Excel spreadsheets to insure pharmacy information is current prior to enumeration of authorizing pharmacies. If the pharmacy has not authorized NCPDP to enumerate the pharmacy NCPDP will not enumerate the pharmacy until the pharmacy does so.

Why is NCPDP asking pharmacies to maintain more information than that needed for getting an NPI?

NCPDP can do all the work required to obtain pharmacy NPI(s) and maintain the NPPES at no additional cost to pharmacy because NCPDP sells the NCPDP Pharmacy Database to industry to recoup its pharmacy NPI enumeration and maintenance costs. The NCPDP Pharmacy Database contains more information than that required by NPPES and has been licensed to industry for over 20 years.

Updated: 7/1/06



Pharmacies benefit from the various industry uses of NCPDP's Pharmacy Database information. Specifically, the entities within the pharmacy industry use this pharmacy information for different business reasons. For example, for affiliating pharmacies with their respective networks or chain headquarters, claims processing, direct mailings of product recalls and publications, network development, health plan directories and rebate information. This information will not be available top industry from NPPES.

How will NCPDP determine which pharmacies to enumerate first? (revised 7/1/06)

NCPDP has worked with CMS and the Enumerator, Fox Systems, Inc. to develop an enumeration plan for pharmacies. NCPDP was asked to submit small files initially and until all processes are tested. Non-chain pharmacies, new pharmacies, and resubmission of rejected records are sent on weekly files to the NPPES system for enumeration. Chain pharmacies are enumerated in batches corresponding with primary relationship codes or "chain codes". Any record issues are triaged between NCPDP, the Enumerator and the pharmacy contact person on the Application.

Effective May 1, 2006, before the NSC can process any Medicare Supplier ID enrollment documentation or make any updates to a supplier file, the supplier must ensure their NPI has been listed on the CMS-855S application. How does this impact NCPDP/s ability to enumerate pharmacies? (revised 7/1/06)

NCPDP has changed our processes so that new pharmacies and pharmacies who change ownership will receive priority when NCPDP submits records to NPPES for NPI enumeration. NCPDP then provides non-chain pharmacies with an email containing the pharmacy NPI to attach to the CMS-855S application. For chain pharmacies, written notification is provided to satisfy this Medicare requirement. For more information on the NPI and CMS-855S applications, please contact Jeannine Deese at ideese@ncpdp.org. It is expected the need for a paper copy of the NPI notification will not be necessary after NPPES dissemination is functional.

What happens if NPPES rejects some of the information submitted by NCPDP? (revised 7/1/06)

If the NPPES system <u>rejects</u> information submitted by NCPDP such as invalid zip code, phone number or address or a potential duplicate submission, NCPDP attempts to correct the error and resubmit the application. NCPDP contacts the individual authorized as the pharmacy "contact person" if NCPDP requires aid in resolving the rejected or pended application record. The most common reason for rejection of independent pharmacy records is "potential duplicate". This means that although the pharmacy gave NCPDP permission to be their EFIO, pharmacies may have already enumerated themselves and the rejection is sent to NCPDP. <u>If NCPDP calls a pharmacy to verify information and clear the pended or rejected record with CMS, it is very important and required by law that the pharmacy aid NCPDP in resolving the matter on a timely basis. This also insures the NCPDP Pharmacy Database is correct and the pharmacy's NPI is on file to avoid payment disruption.</u>



If NPPES <u>pends</u> the information on a record for Enumerator review, then the Enumerator contacts NCPDP or the pharmacy to receive clarification, if necessary and either accepts or rejects the record. If rejected, the record can be corrected and resubmitted.

If NPPES rejects an <u>entire NCPDP submission</u> on behalf of a chain or other affiliate because it contains an unusual number of errors, NCPDP retains the right to request that chain or affiliate resolve the errors and resubmit a file to NCPDP. Pharmacies are responsible for the quality and validity of the information provided.

How important is it that NCPDP has current information on pharmacies? (revised 7/1/06)

Federal Law requires that pharmacies certify the information submitted to NPPES is correct and that changes are sent to NPPES within 30 days of a change. For this reason, NCPDP is requesting pharmacies fill out the form at http://www.ncpdp.org/frame_news_npi-info.htm and update NCPDP within 20 days of a change of information. The Form provides a method for individual pharmacies to certify the information is correct. NCPDP will also require those sending the Excel Template file to certify the information sent to NCPDP is correct.

Our organization has downloaded the Excel Template. Can we just cut and paste from other lists or spreadsheets to provide the information NCPDP needs? (revised 7/1/06)

Yes. As long as all periods, apostrophes, dashes, ampersands & # symbols are removed. Make sure these characters are removed from the legal business name, dba name, physical address1, contact name, cross streets, mailing address 1 &2, mailing city, and state license fields. Follow the instructions carefully to avoid the need for more clean-up. NCPDP suggests a sample file with a dozen records or so are sent for review prior to an entire Excel File

What is the process once files are sent to NPPES and the Enumerator? How soon will our organization receive our NPI(s) (revised 7/1/06)

NPPES sends a response file 6 days after NCPDP sends the submission file. Records on the response file can either be enumerated, rejected or pended to the Enumerator. NCPDP researches and resubmits rejected records. This sometimes requires calling the pharmacy and working with the pharmacy to resolve the problem. The Enumerator resolves pended records. The Enumerator contacts NCPDP and/or the pharmacy contact person to aid in resolution. Pended records that have been finalized are sent on another file 6 days later. It is very important as a Federal requirement that pharmacies respond to calls from NCPDP or the Enumerator to resolve these pended records.

Remember, the 6-day turnaround time is for the NPPES first and all future response files as a result of the original submission. NCPDP notifies pharmacies of their NPI on enumerated records. In the case of independents, an email is sent. From NPI EFIO@ncpdp.org. In the case of chains, an email and file of NPIs is sent once all pharmacies are enumerated. Keep this email as some payers or processors may

National Council for Prescription Drug Programs NCPDP

FAQs on NPI Enumeration

require a copy including Medicare when enrolling/changing information related to the Medicare Supplier ID.

How are pharmacies notified of their NPI(s)? (revised 7/1/06)

After obtaining a file's NPIs, NCPDP notifies pharmacies (or chain headquarters of the pharmacy if it is part of a chain) of their NPI(s) via email. Please watch for an email from NPI EFIO@ncpdp.org. NCPDP plans to have all authorizing pharmacies enumerated by late fall 2006 and will then begin outreach to pharmacies for which no NPI is on file. If a pharmacy is late in sending information to NCPDP, the pharmacy will be enumerated later. Enumeration is an ongoing process and will not cease. The NPI must be used on all HIPAA transactions by May 23, 2007. Therefore, NCPDP and its members recommend all pharmacies obtain NPIs by December 2006. Industry needs adequate time for testing prior to May 2007.

After getting NPIs from NCPDP, what are a pharmacy's responsibilities in the future?

Over time, information on pharmacies may change. It is the pharmacy's or chain headquarter's responsibility to notify NCPDP of changes as soon as possible so that NCPDP can update NPPES within 30 days as required by Federal law.

How often should a pharmacy update information with NCPDP?

NCPDP recommends pharmacies submit an update form to NCPDP or an updated file within 10 days of a change in information or annually if information has not changed.

Our pharmacy already has an NPI. What do we do?

If a pharmacy already has an NPI, pharmacies can still authorize NCPDP to maintain data in NPPES for them. Simply fill out the NCPDP Application Form on the NCPDP website at http://www.ncpdp.org/frame_news_npi-info.htm, provide the NPI in the proper space, check the authorization box in Section 11 and sign the NPI authorization line. If a pharmacy wished to maintain NPPES information itself, but wants to insure information and NPI on the NCPDP Pharmacy Database are correct, fill out the same form, provide the NPI on the application, do not check the authorization box or sign the NPI authorization line, and send or fax the application form to NCPDP.

If one of our group of pharmacies has already applied (separately) and received an NPI, will the one that NCPDP gives us when the EFIO enumeration occurs replace that NPI? What if we don't know that a pharmacy has already obtained a number? (revised 7/1/06)

If a pharmacy already has an NPI and NCPDP does not have the number on our database, NCPDP will attempt to submit for an NPI on behalf of that pharmacy. The NPPES system will pend or deny the record as a potential or exact duplicate. If a chain or group of pharmacies is aware of NPIs for some in the group, please provide them to

National Council to Programs NCPDP

FAQs on NPI Enumeration

NCPDP to avoid this situation. If not, after some research, the actual NPI of the pharmacy will be determined and the duplicate record will be denied in NPPES.

If our organization authorizes NCPDP to be our EFIO, must we also use NCPDP for ongoing maintenance?

Pharmacies can notify NCPDP if they wish to rescind authorization. NCPDP contacts the Enumerator, Fox Systems, Inc. who provides pharmacies with a log-on ID and password for the NPI website for each pharmacy that wishes to maintain their own information after previously authorizing NCPDP. If this option is chosen, NCPDP asks that the pharmacy maintain information with NCPDP as in the past so that the Database reflects accurate information.

CMS requires that the pharmacy notify NPPES within 30 days of a change of address or other information. The easiest way to do this is to notify NCPDP using the proper form on the NCPDP website. NCPDP will update the NCPDP Pharmacy Database and update NPPES (CMS).

What is a taxonomy code and where will we find them? (revised 7/1/06)

Taxonomy codes describe the type and specialty of providers. A minimum of one taxonomy code is required for obtaining an NPI. The NCPDP Pharmacy Database has been modified to carry up to 15 taxonomy codes per pharmacy. This is an example of additional information NCPDP needs from pharmacies prior to enumerating a pharmacy.

Taxonomy codes are codes maintained by the National Uniform Claim Committee (NUCC) to describe provider types and specialties. There are currently twelve (12) taxonomy codes for pharmacies as well as other specialties such as DME. They are listed at www.wpc-edi.com/taxonomy. If a pharmacy applies for their own NPI, pharmacies will need to include these code(s) on the NPI application. If NCPDP is applying for a pharmacy's NPI on their behalf, check the appropriate pharmacy taxonomy codes on the NCPDP application form.

Can a pharmacy have multiple NCPDP numbers? For example, if pharmacies are performing multiple services (LTC vs. Retail vs. Home Infusion), could a pharmacy have an NCPDP number and NPI for each? Moreover, would it depend on what types/numbers of state licenses or taxonomies that the pharmacy has? (revised 7/1/06)

Although NCPDP has always had a policy of one NCPDP Provider ID for each pharmacy and that has generally worked in the past, the NPI Final Rule does allow organizational providers to have more than one NPI. This does not apply to individuals or sole proprietorships. The most frequent example of this will be an NPI for the pharmacy and a separate NPI for DME. With the exception of DME, NCPDP discourages the use of multiple NPIs for a pharmacy as it goes against administrative simplification and often there are other attributes of a standard claim that can indicate whether the pharmacy is performing services as community/retail, long term care or a home infusion pharmacy. If



a pharmacy is unsure of what to do, contact jdeese@ncpdp.org and NCPDP will work with the pharmacy to determine the best coarse of action.

Our pharmacy also sells DME supplies. Do we need a second NPI? (revised 7/1/06)

No. Medicare requires providers have a separate DME NPI for each location. However, the DME NPI can be the same as that location's pharmacy NPI. This is the provider's choice. Please include the appropriate taxonomy code(s) on the application. Taxonomies are maintained in the NCPDP Pharmacy Database and submitted to NPPES. If, a pharmacy currently has two NCPDP Provider ID numbers for business reasons (one for pharmacy and one for DME), NCPDP recommends pharmacies obtain a second NPI corresponding with the second NCPDP Provider ID number and include the appropriate taxonomy under each number.

Our pharmacy currently has two NCPDP ID numbers for different operations. Do we need two NPIs? (updated 3/2/06)

No. However, if a pharmacy currently has two NCPDP ID numbers, NCPDP recommends the pharmacy apply for two NPIs. Pharmacies are organizations and organizations can have more than one NPI for their respective "subparts".

There is a chance NPPES will reject or pend the second application as a possible duplicate. NCPDP will work with the Enumerator, Fox Systems, that the pharmacy or pharmacy headquarters to allow the second NPI. Make sure the Taxonomy Code/Business Type section on the application is different for each application to describe the respective business subpart operation.

Industry has developed taxonomy codes (including LTC) so pharmacies can more clearly describe the services pharmacies perform. They are on the NCPDP application. Additional codes are available at http://www.wpc-edi.com/taxonomy.

Does the NCPDP Database design allow for more than one NCPDP number to be linked to the same NPI; or will it allow different NCPDP numbers to be linked to the same NPI at different times? (revised 7/1/06)

No. Only one NPI can be assigned to each NCPDP Provider ID and only one NCPDP Provider ID is assigned to any given NPI. If an NPI or NCPDP Provider ID is deactivated due to a store closing or change in ownership, the corresponding number is deactivated as well. In the case of a change in ownership, it is the decision of the sellers and buyers whether the buyer will retain the seller's NCPDP ID and NPI. If the buyer is to retain the seller's identifiers, the seller must provide NCPDP with written and notarized permission that the buyer can retain the identifiers. The transaction is reflected on the next monthly file sent to subscribers. A given NCPDP Provider ID and NPI are always linked; although EINs, relationship codes and other information related to those numbers may change.

Does a change in ownership require a change in NCPDP numbers? (revised 7/1/06)



Current rules will continue to be effective. A change in ownership does not require a change in identifiers. Whether or not there is a change of identifiers is a condition of the sale. The seller must notify NCPDP if the buyer is to retain the identifiers and the notification must be notarized. If an NPI is to be deactivated, only the pharmacy or chain headquarters is authorized by CMS to do so.

What if a pharmacy deactivates their NCPDP ID and NPI and later needs to reinstate the numbers? (revised 7/1/06)

I the past, NCPDP was able to re-instate a pharmacy with its original number relatively easily. This may not be the case with an NPI. It is not known at this time whether there is the ability to reinstate a deactivated NPI. Please contact NCPDP if the pharmacy encounters this situation and we will contact CMS to determine how best to solve the problem.

When should pharmacies begin using NPIs instead of NCPDP Provider ID Numbers? (updated 3/2/06)

The Workgroup on Electronic Data Interchange (WEDi) and NCPDP members have drafted a white paper that includes guidance for the industry and a timeline for the pharmacy industry for transition from the current NCPDP Provider Pharmacy ID to the NPI. Testing between pharmacies, processors and other trading partners will begin in late 2006. Certification testing and production use of the NPI is scheduled to begin in January 2007 with full transition to the NPI by May 23, 2007. After that date, the NPI must be used on all HIPAA covered transactions. The finalized white paper is available at www.wedi.org and on the NCPDP website at http://www.ncpdp.org/pdf/NPI_NCPDP_impact_on_phcy_services_sector_NCPDP_white_papers_2005-12-19.pdf. It also contains more detail on NPI implementation issues.

Does the NPI replace NCPDP Provider ID numbers on a HIPAA standard transaction such as a v5.1 claim?

Yes. Using the industry timeline, once a pharmacy's trading partners are "live", the NPI will replace the NCPDP ID on the HIPAA transaction. During the transition period in early 2007, it is possible that a pharmacy will need to submit the NCPDP ID on some claims to certain claims processors and the NPI to others. Please verify that your pharmacy system software is able to perform in this manner. Note that in addition to claims, the NPI will be used on standard HIPAA transactions including eligibility and prior authorization transactions. Note that this affects the real-time Telecommunication transactions, as well as the Batch Standard submissions.

When should pharmacies update data with NCPDP? (revised 7/1/06)

The time is now. Updating pharmacy information now will place the pharmacy in the enumeration queue maintained by NCPDP. After bulk enumeration, Federal Law requires that the NPPES be updated within 30 days of a change in information. NCPDP



encourages pharmacies to update NCPDP as soon as possible to insure the change meets the 30-day window. For pharmacy chains, NCPDP recommends chains provide NCPDP with one file that includes all updated information each month and another file with new stores to obtain NPIs

What should pharmacies be doing now to prepare for NCPDP's submission? (revised 7/1/06)

If the organization represents many pharmacies, NCPDP recommends obtaining the new standard NCPDP Excel™ Template at http://www.ncpdp.org/frame_news_npi-info.htm. Begin collecting the data needed from the appropriate sources and submit the file as soon as possible. An individuals pharmacy or small chain can download the new NCPDP Provider ID and NPI Application Form now at http://www.ncpdp.org/frame_news_npi-info.htm and submit data to NCPDP so that data is current.

When gathering information for the application, double check to insure that all information, such as demographic information, phone, fax, Taxonomy/Business Types, DEA, Medicaid, Medicare, Federal Employer Identification Numbers, are correct. This will reduce rejected applications and aid in resolving any potential duplicate issues.

Now that NCPDP is live and enumerating pharmacies, when will NCPDP add the NPI to the NCPDP Pharmacy Database and when that information will start to be provided to the subscribers of that file? (revised 7/1/06)

NCPDP has enhanced the database to provide the NPI among other data elements on pharmacies as in the past. Subscribers must modify their systems and obtain the NCPDP v2.0 Processor Set to receive the NPI. Please contact Jeannine Deese at ideese@ncpdp.org to begin receiving the v2.0 output file. The Pharmacy Database v2.0 Implementation Guide is available at http://www.ncpdp.org/frame_news_npi-info.htm.

Where can pharmacies learn more about NCPDP's progress with NPI enumeration? (revised 7/1/06)

The best place to learn the current status of NCPDP's progress with NPI enumeration is the NCPDP website. Go to www.ncpdp.org for information related to NCPDP's EFIO activities, updates to this FAQ document and applications. This will site be updated at least monthly. In addition, pharmacies will receive information periodically through NCPDP Now, e-mails, industry publications and other associations. If a pharmacy wishes to receive broadcast emails specific to NPI enumeration progress, please notify kdeininger@ncpdp.org and NCPDP will add the organization's email name to the broadcast email list.

Who should pharmacies contact if they have more questions?

Please e-mail Jeannine Deese, NCPDP Manager of Pharmacy Services at ideese@ncpdp.org. Please e-mail the question and it will be answered via return e-mail.



California State Board of Pharmacy

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834 Phone (916) 574-7900 Fax (916) 574-8618 www.pharmacy.ca.gov STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To:

Licensing Committee

Date: November 27, 2006

From:

Board of Pharmacy

Subject:

Competency Committee Report

Test Administration Contract

The Office of Examination Resources (OER) within the Department of Consumer Affairs is seeking a new contract with a vendor to provide computer based testing through a Request for Proposal (RFP) process. The board uses this contract to administer the CPJE. The current contract expires December 1, 2006.

The second Request for Proposal (RFP) was cancelled effective November 8, 2006. OER has received approval to extend the current contract with Thomson Prometric to extend services from December 1, 2006, to May 31, 2007. A third RFP will be developed to begin services June 1, 2007.

CPJE Pass Rate Summary

A total of 1633 applicants took the CPJE in fiscal year 2005/06. Of the 1633 applicants, 325 failed the CPJE while 1308 passed the CPJE. The pass rate for the CPJE in fiscal year 2005/06 is 80%.

Competency Committee Structure Update

The current Competency Committee consists of representatives from different pharmacy settings. There are two board members, two board inspectors, 12 community practitioners, 10 institutional practitioners and four academic practitioners.

At the August meeting, the committee structure was bifurcated to increase the efficiency of the examination development. Since the committee restructure, each subcommittee has met once this year to work on exam development. The committee has set the dates for exam development meetings in 2007.

Memorandum

Licensing Committee To:

Date: November 27, 2006

From: Board of Pharmacy

Subject: CE for Taking the Certification Examination for Geriatric Pharmacy

Background:

Pharmacists are required to earn 30 hours of approved CE every two years as a condition of license renewal. Currently pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05).
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE)
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings)
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 units)

Proposal:

The Commission for Certification in Geriatric Pharmacy (CCGP) offers a program for pharmacists to become Certified Geriatric Pharmacists. There are currently 1,300 certified geriatric pharmacists in the United States, Canada, Australia and other countries.

To become certified, the individual must pass a 3-hour, 150-question examination covering three major areas: Patient Specific, Disease Specific and Population Specific activities. The exam has been psychometrically validated by a firm specializing in such processes.

Two states, Ohio and Washington, recognize CCGP's certification examination for continuing education credits. Recently the board was notified about this examination and was asked to consider its appropriateness for continuing education (CE) credit.

I have provided background material about the CCGP certification examination in this tab section.

Q: Does the committee wish to recommend CE for proof of completing/passing the CCGP exam?

Comment:

The board's legal counsel now advises that the board needs to adopt a regulation to authorize the award of CE for board meetings, committee meetings and the PSAM. Accordingly, such a regulation will be brought to the January Legislation and Regulation Committee.

If Licensing Committee recommends, and the board agrees, to award CE for the CCGP exam, staff will add a provision to the proposed regulation.



September 5, 2006

Patricia F. Harris California Board of Pharmacy 1625 N Market Boulevard, N219 Sacramento, CA 95834

Dear Ms. Harris:

I am writing to request that the California Board of Pharmacy consider recognition of our certification examination as at least one approved source for purposes of meeting the Pharmacy Board's current Continuing Education requirements.

At present, at least two states, Ohio and Washington, recognize CCGP's certification examination for continuing education credits. We are seeking similar recognition among the other state boards of pharmacy.

Our examination is 3 hours and is composed of 150 multiple choice questions addressing three major domains: Patient Specific, Disease Specific, and Population Specific activities. It has been structured according to currently excepted psychometric principles and is administered on our behalf by Applied Measurement Professionals (AMP), one of the major psychometric firms in the United States. The exam, itself, is based upon a detailed content outline that was produced from a Practice Analysis in 2003. I have enclosed a copy of our current Candidate Handbook. It provides an outline of that Content Map. The Candidate Handbook also provides a brief description of CCGP and sets forth the rules and policies for earning and maintaining certification.

Our certification is the only population specific specialty designation in the pharmacy profession and has been awarded to more than 1,300 board Certified Geriatric Pharmacists, in good standing who practice in the United States, Canada, Australia and other international locations. We believe that CCGP certification is tangible evidence that a board Certified Geriatric Pharmacist is uniquely qualified to provide pharmacy care to the frail and elderly. Furthermore, while the new Medicare Part D program is still in its infancy, we are beginning to see evidence that CCGP certification is becoming at least one criterion for selecting pharmacists for participation on Pharmacy and Therapeutics Committees and networks of providers used by Pharmacy Benefit Managers and Prescription Drug Plans to provide drug benefit services.

We would appreciate the Board's willingness to consider our request. Please feel free to visit our website www.ccgp.org for more information, including the ability to download our Candidate Handbook. If you have any questions, you can contact me by email at <a href="https://link.org

Sincerely,

..... Lance O. Hoxie

/ Jaxel G. House

COMMISSION FOR CERTIFICATION Executive Director

IN GERIATRIC PHARMACY

Examination

Examination

in

Geriatric

Plantage



Sponsored by Commission for Certification in Geriatric Pharmacy (CCGP)

January 2006

Candidate Handbook • Candidate Handbook

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All questions and requests for information about CCGP Certification should be directed to:

CCGP 1321 Duke Street Alexandria, VA 22314-3563 703/535-3036 FAX 703/739-1500 All questions and requests for information about examination scheduling should be directed to:

Applied Measurement Professionals, Inc. 8310 Nieman Road Lenexa, KS 66214 Voice: 913/541-0400

Fax: 913/541-0156 Website: www.goAMP.com

ABOUT CCCP

The Commission for Certification in Geriatric Pharmacy (CCGP) is a nonprofit corporation created in February 1997 by the American Society of Consultant Pharmacists (ASCP) Board of Directors. CCGP was created to oversee the certification program in geriatric pharmacy by establishing eligibility criteria and other program policies.

The CCGP Board of Commissioners is comprised of seven elected pharmacists; three appointed commissioners (consumer, and payor representative, and a physician with experience and/or credentialing in geriatric practice); one representative appointed by the American Society of Consultant Pharmacists (ASCP) Board of Directors, the ASCP Executive Director, and the CCGP Executive Director (ex officio). The membership of CCGP is comprised of individuals who have passed the Certification Examination in Geriatric Pharmacy and are credentialed.

ABOUT THE HANDEOOK

This Candidate Handbook is only a guide. The information, procedures and fees detailed in this publication may be amended, revised or otherwise altered at any time and without advance notice by CCGP. The provision of this handbook does not confer any rights upon the applicant. For the most current version of this handbook, please visit www.goAMP. com.

STATEMENT OF MONDISCRIMINATION POLICY

CCGP does not discriminate among applicants on the basis of age, gender, race, religion, national origin, disability, sexual orientation or marital status.

CERTECATION

The certification program in geriatric pharmacy is intended to recognize those pharmacists who demonstrate knowledge of geriatric pharmacotherapy and the knowledge and skills required to provide pharmaceutical care to the elderly. These pharmacists may practice in a variety of settings, including hospital, community or long-term care.

Applied Measurement Professionals, Inc. (AMP) is the professional testing agency contracted by CCGP to assist in the development, administration, scoring and analysis of the certification examination. AMP services also include the reporting of scores to candidates who take the examination. AMP is a research and development firm that conducts professional competency assessment research and provides examination services for a number of credentialing programs.

EXAMINATION POLICIES

CCGP offers the *Certification Examination in Geriatric Pharmacy* to individuals in geriatric pharmacy practice. The examination consists of 150 multiple-choice questions. Candidates will be allowed three hours to complete the examination. Individuals passing the Certification Examination in Geriatric Pharmacy are credentialed as Certified Geriatric Pharmacists (CGP).

CCGP with the advice and assistance of AMP prepares the examinations. Individuals with expertise in geriatric pharmacy practice write the questions and review them for relevancy, consistency, accuracy and appropriateness.

ELIGIBILITY REQUIREMENTS

To be eligible for the Certification Examination in Geriatric Pharmacy, an applicant must currently be a licensed pharmacist and must have a minimum of two years of experience as a licensed pharmacist. Applications must be accompanied by:

- a photocopy of current state pharmacy registration certificate/license, and
- 2) a check, money order or credit card payment.

AUDIT PROCEDURE

CCGP reserves the right to audit any application submitted for the Certification Examination in Geriatric Pharmacy.

FOREIGN TRAINED/FOREIGN LICENSED APPLICANTS

Pharmacists who are not licensed to practice pharmacy in the United States may apply to take the Certification Examination in Geriatric Pharmacy. However, the practice analysis upon which the examination is based was conducted in the United States and CCGP does not claim that these processes or certification are accepted or recognized outside of the United States. Applicants who are not licensed to practice pharmacy in the United States must provide notarized documentation of their legal authorization to practice pharmacy in another country.

APPLICATION FEE

The Application Fee for the examination is \$600. Fees may be paid by check or money order (made payable to CCGP), or by credit card (VISA, MasterCard, Discover or American Express). DO NOT SUBMIT CASH.

Candidates must submit the appropriate fee with the application form.

Returned checks and/or declined credit card transactions will be subject to a \$25 handling fee. You must send a certified check or money order for the amount due, including the NSF fee, to CCGP to cover returned check and/or declined credit card transactions.

EXAMINATION ADMINISTRATION

The examination is delivered by computer at over 150 AMP Assessment Centers geographically located throughout the United States, Canada and Australia. Generally, there are no application deadlines and a candidate may submit an Application and Application Fee at any time. Testing is normally the first full week of each month. The examination is administered by appointment only Monday through Friday at 9:00 a.m. and 1:30 p.m. Available dates will be indicated when scheduling your examination. Candidates are scheduled on a first-come, first-served basis.

HOLIDAYS

The examinations are not offered on the following holidays:

New Year's Day
Martin Luther King Day
Presidents' Day
Good Friday
Memorial Day
Independence Day (July 4)
Labor Day
Columbus Day
Veterans' Day

Thanksgiving Day (and the following Friday)

Christmas Eve Day

Christmas Day

New Year's Eve Day

REGISTERING FOR AN EXAMINATION

Candidates should ensure that the CCGP Application has been properly completed and that the information provided is accurate. Your careful attention will enable prompt and efficient processing. Candidates will not be able to schedule an examination appointment with AMP until the Application has been processed. AMP will send written notification to registered candidates with examination scheduling procedures.

SCHEDULING AN EXAMINATION

After the candidate has received written confirmation from CCGP, there are two ways to schedule an appointment for the examination.

- 1. Schedule Online: The candidate may schedule an examination appointment online at any time by using AMP's online application/scheduling service. To use this service, follow these easy steps:
 - Go to www.goAMP.com and select "Candidates."
 - Follow the simple, step-by-step instructions to select your examination program and schedule an examination.

2. Telephone Scheduling: Call AMP at 888/519-9901 to schedule an examination appointment. This toll-free number is answered from 7:00 a.m. to 7:00 p.m. (Central Time) Monday through Thursday, 7:00 a.m. to 5:00 p.m. on Friday and 8:30 a.m. to 5:00 on Saturday.

When scheduling an examination, be prepared to confirm a location, a preferred date and time for testing, and to provide your Social Security number as a unique identification number. AMP will use your Social Security number only as an identification number in maintaining your record. When you contact AMP to schedule an examination appointment, you will be notified of the time to report to the Assessment Center. Please make a note of it because you will NOT receive an admission letter.

If you call AMP by 3:00 p.m. Central Time on	Depending on availability, your examination may be scheduled beginning
Monday	Thursday
Tuesday	Friday
Wednesday	Monday
Thursday	Tuesday
Friday	Wednesday

ASSESSMENT CENTER LOCATIONS

AMP Assessment Centers have been selected to provide accessibility to the most candidates in all states and major metropolitan areas. AMP Assessment Centers are typically located in H&R Block offices. International locations are also offered in Canada and Australia. A current listing of AMP Assessment Centers, including addresses and driving directions, may be viewed at AMP's website located at www.goAMP.com. Specific address information will be provided when a candidate schedules an examination appointment.

SPECIAL ARRANGEMENTS FOR CANDIDATES WITH DISABILITIES

CCGP and AMP comply with the Americans with Disabilities Act and strive to ensure that no individual with a disability is deprived of the opportunity to take the examination solely by reason of that disability. CCGP and AMP will provide reasonable accommodations for candidates with disabilities.

Wheelchair access is available at all Assessment Centers. Candidates with visual, sensory or physical disabilities that would prevent them from taking the examination under standard conditions may request special accommodations and arrangements. Candidates testing with approved special accommodations should schedule their test via AMP's toll-free number to ensure their accommodations are confirmed. Be sure to inform CCGP and AMP of your need for special accommodations when calling to schedule your examination.

TELECOMMUNICATION DEVICES FOR THE DEAF

AMP is equipped with Telecommunication Devices for the Deaf (TDD) to assist deaf and hearing-impaired candidates. TDD calling is available 8:30 a.m. to 5:00 p.m. (Central Time) Monday-Friday at 913/495-4437. This TDD phone option is for individuals equipped with compatible TDD machinery.

EXAMINATION APPOINTMENT CHANGES

A candidate may reschedule an examination appointment at no charge **once** by calling AMP at 888/519-9901 at least four business days prior to the scheduled testing session. (See table below.)

If the examination is scheduled on	AMP must be contacted by 3:00 p.m. Central Time to reschedule the examination by the previous
Monday	Tuesday
Tuesday	Wednesday
Wednesday	Thursday
Thursday	Friday
Friday	Monday

MISSED APPOINTMENTS AND CANCELLATION

A candidate will forfeit the examination registration and all fees paid to take the examination under the following circumstances.

- The candidate wishes to reschedule an examination but fails to contact AMP at least four business days prior to the scheduled testing session,
- The candidate wishes to reschedule a second time,
- The candidate appears more than 15 minutes late for an examination, or
- The candidate fails to report for an examination appointment.

A complete Application and appropriate fee are required to reregister for the examination.

INCLEMENT WEATHER, POWER FAILURE OR EMERGENCY

In the event of inclement weather or unforeseen emergencies on the day of an examination, AMP will determine whether circumstances warrant the cancellation, and subsequent rescheduling, of an examination. The examination will usually not be rescheduled if the Assessment Center personnel are able to open the Assessment Center. If power to an Assessment Center is temporarily interrupted during an administration, your examination will restart where you left off and you may continue the examination.

Candidates may contact AMP's Weather Hotline at 913/495-4418 (24 hours/day) prior to the examination to determine if AMP has been advised that any Assessment Centers are closed. Every attempt is made to administer the examination as scheduled; however, should an examination be canceled at an Assessment Center, all scheduled candidates will receive notification following the examination regarding rescheduling or reapplication procedures.

PREPARING FOR THE EXAMINATION

Your primary objective in preparing for the examination is to pass. Other objectives such as learning new material and reviewing old material are critical toward this objective. Begin your study by developing your strategy for success.

A good study strategy includes preparation. To prepare, determine first what you need to learn, choose your study materials, and select a quiet, comfortable place that allows you to focus. Before you begin, check to make sure you have everything you need. Try to avoid interruptions for any reason.

Developing a study plan will allow you to learn the most as you study. Include setting goals in your study plan. Review what you have studied as often as possible. The more you review, the more you will retain.

Candidates may also wish to purchase CCGP's Self-Assessment Examination (SAE). The SAE is designed to help pharmacists measure their knowledge and skills in geriatric pharmacy practice. It will help identify those areas where additional continuing education may be helpful. It will also provide a candidate with a simulated experience in undertaking the actual certification examination. Once areas of additional continuing education would be helpful, candidates may wish to take advantage of a variety of resources such as www.geriatriacpharmacyreview.com to supplement existing knowledge. Please see page 13 for more information concerning the SAE.

TAKING THE EXAMINATION

Your examination will be given by computer at an AMP Assessment Center. You do not need any computer experience or typing skills to take your examination. On the day of your examination appointment, report to the Assessment Center no later than your scheduled testing time. Look for the signs indicating AMP Assessment Center Check-in. A CANDIDATE WHO ARRIVES MORE THAN 15 MINUTES AFTER THE SCHEDULED TESTING TIME WILL NOT BE ADMITTED.

IDENTIFICATION

To gain admission to the Assessment Center, you must present two forms of identification, one with a current photograph. Both forms of identification must be current and include the candidate's current name and signature. The candidate will be required to sign a roster for verification of identity.

Acceptable forms of photo identification include a current driver's license with photograph, a current state identification card with photograph, a current passport, or a current military identification card with photograph. Employment ID cards, student ID cards and any type of temporary identification are NOT acceptable as the primary form of identification.

You must have proper identification to gain admission to the Assessment Center. Failure to provide appropriate identification at the time of the examination is considered a missed appointment. There will be no refund of your examination fee.

SECURITY

CCGP and AMP maintain examination administration and security standards that are designed to assure that all candidates are provided the same opportunity to demonstrate their abilities. The Assessment Center is continuously monitored by audio and video surveillance equipment for security purposes.

The following security procedures apply during the examination:

- Examinations are proprietary. No cameras, notes, tape recorders. Personal Digital Assistants (PDAs), pagers or cellular phones are allowed in the testing room.
- Hand-held, silent, non-printing, battery-operated calculators may be used. Candidates may NOT use calculators which have either word processing or word storage capabilities (complete A-Z keypad). All calculators will be examined by the proctor before a candidate is admitted to the examination area. Candidates are responsible for providing their own calculators. Candidates cannot share calculators during the examination.
- No guests, visitors or family members are allowed in the testing room or reception areas.
- No personal items, valuables, or weapons should be brought to the Assessment Center. Only keys and wallets may be taken into the testing room and AMP is not responsible for items left in the reception area.

EXAMINATION RESTRICTIONS

- No personal belongings will be allowed in the Assessment Center. Pencils will be provided during check-in.
- You will be provided with scratch paper to use during the examination. You must return the scratch paper to the supervisor at the completion of testing, or you will not receive a score report. No documents or notes of any kind may be removed from the examination room.

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- No questions concerning the content of the examination may be asked during the examination.
- Eating, drinking or smoking will not be permitted in the Assessment Center.
- You may take a break whenever you wish, but you will not be allowed additional time to make up for time lost during breaks.

MISCONDUCT

Individuals who engage in any of the following conduct may be dismissed from the examination, their scores will not be reported and examination fees will not be refunded. Examples of misconduct are when a candidate:

- · creates a disturbance, is abusive, or otherwise uncooperative:
- displays and/or uses electronic communications equipment such as pagers, cellular phones, PDAs;
- gives or receives help or is suspected of doing so;
- attempts to record examination questions or make notes;
- attempts to take the examination for someone else; or
- is observed with notes, books or other aids.

COPYRIGHTED EXAMINATION **OUESTIONS**

All examination questions are the copyrighted property of CCGP. It is forbidden under federal copyright law to copy, reproduce, record, distribute or display these examination questions by any means, in whole or in part. Doing so may subject you to severe civil and criminal penalties.

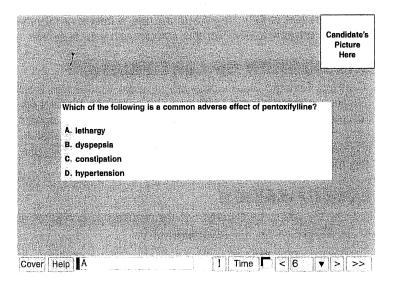
PRACTICE EXAMINATION

After your identification has been confirmed, you will be directed to a testing carrel. You will be instructed on-screen to enter your Social Security number. You will take your photograph which will remain on screen throughout your examination session. This photograph will also print on your score report.

Prior to attempting the examination, you will be given the opportunity to practice taking an examination on the computer. The time you use for this practice examination is NOT counted as part of your examination time or score. When you are comfortable with the computer testing process, you may quit the practice session and begin the timed examination.

TIMED EXAMINATION

Following the practice examination, you will begin the timed examination. Before beginning, instructions for taking the examination are provided on-screen.



The computer monitors the time you spend on the examination. The examination will terminate if you exceed the time allowed. You may click on the "Time" box in the lower right-hand corner of the screen or select the Time key to monitor your time. A digital clock indicates the time remaining for you to complete the examination. The Time feature may be turned off during the examination.

Only one examination question is presented at a time. The question number appears in the lower right hand corner of the screen. Choices of answers to the examination question are identified as A, B, C, or D. You must indicate your choice by either typing in the letter in the response box in the lower left hand of the computer screen or clicking in the option using the mouse. To change your answer, enter a different option by pressing the A, B, C, or D key or by clicking on the option using the mouse. You may change your answer as many times as you wish during the examination time limit.

To move to the next question, click on the forward arrow (>) in the lower right portion of the screen or select the NEXT key. This action will move you forward through the examination question by question. If you wish to review any question or questions, click the backward arrow (<) or use the left arrow key to move backward through the examination.

An examination question may be left unanswered for return later in the examination session. Questions may also be bookmarked for later review by clicking in the blank square to the right of the Time button. Click on the hand icon or select the NEXT key to advance to the next unanswered or bookmarked question on the examination. To identify all unanswered and bookmarked questions, repeatedly click on the hand icon or press the NEXT key. When the examination is completed, the number of examination questions answered is reported. If not all questions have been answered and there is time remaining, return to the examination and answer those questions. Be sure to provide an answer for each examination question before ending the examination. There is no penalty for guessing.

CANDIDATE COMMENTS

During the examination, online comments may be provided for any question by clicking on the button displaying an exclamation point (!) to the left of the Time button. This opens a dialogue box where comments may be entered. Comments will be reviewed, but individual responses will not be provided.

FOLLOWING THE EXAMINATION

After completing the examination, candidates are asked to complete a short evaluation of their examination experience. Then, candidates are instructed to report to the examination proctor to receive their score report. Scores are reported in written form only, in person or by U.S. mail. Scores are not reported over the telephone, by electronic mail or by facsimile.

Your score report will indicate a "pass" or "fail." Your pass/fail status is determined by your raw score. Additional detail is provided in the form of raw scores by major content category. A raw score is the number of questions you answered correctly.

PASS/FAIL SCORE DETERMINATION

Examination scores are reported as raw scores and scaled scores. A raw score is the number of correctly answered questions; a scaled score is statistically derived from the raw score. Your total score determines whether you pass or fail; it is reported as a scaled score ranging between 0 and 99.

The minimum scaled score needed to pass the examination has been set at 75 scaled score units. The reason for reporting scaled scores is that different forms (or versions) of the examination may vary in difficulty. As new forms of the examination are introduced each year, a certain number of questions in each content area are replaced. These changes may cause one form of the examination to be slightly easier or harder than another form. To adjust for these differences in difficulty, a procedure called "equating" is used. The goal of equating is to ensure fairness to all candidates.

In the equating process, the minimum raw score (number of correctly answered questions) required to equal the scaled passing score of 75 is statistically adjusted (or equated). For instance, if the examination is determined to be more difficult than the previous form of the examination, then the minimum raw passing score required to pass will be slightly lower than the original raw passing score. If the examination is easier than the previous form of the examination, then the minimum raw score will be higher. Equating helps to assure that the scaled passing score of 75 represents the same level of competence no matter which form of the examination a candidate takes.

In addition to the candidate's total scaled score and scaled score required to pass, raw scores (the actual number of questions answered correctly) are reported for the major categories on the content outline. The number of questions answered correctly in each major category is compared to the total number of questions possible in that category on the score report (e.g., 15/20). Content categorical information is provided to assist candidates in identifying areas of relative strength and weakness; however, passing or failing the examination is based only on the candidate's total scaled score.

SCORES CANCELLED BY CCGP OR AMP

CCGP and AMP are responsible for the validity and integrity of the scores they report. On occasion, occurrences, such as computer malfunction or misconduct by a candidate, may cause a score to be suspect. CCGP and AMP reserve the right to void or withhold examination results if, upon investigation, violation of its regulations is discovered.

IF YOU PASS THE EXAMINATION

If you pass the examination, CCGP will request that you sign a Declaration on the Appropriate use of the Credential and remit a five-year certification fee. Following receipt of the Declaration and fee, CCGP will send a Certificate, in your name, officially designating you as a Certified Geriatric Pharmacist.

IF YOU DO NOT PASS THE EXAMINATION

There is no limit to the number of times candidates may attempt the examination. If you were unsuccessful in your examination attempt, you may reregister once every 90 days by completing another Application and submitting appropriate fees. The fee to retake the examination after an unsuccessful attempt is \$300, if the examination is retaken within two years. After two years, the full fee (\$600) must be paid.

FAILING TO REPORT FOR AN EXAMINATION

A candidate who fails to report for an examination forfeits all fees paid to take the examination. A completed application and examination fee are required to reapply for examination.

CONFIDENTIALITY

Information about candidates for testing and their examination results are considered confidential. Individual examination scores are released ONLY to the individual candidate. Questions concerning examination results should be referred to the CCGP Candidate Services Department in writing.

RECOGNITION OF CERTIFICATION

Candidates who pass the certification examination are entitled to use the designation "CGP" for Certified Geriatric Pharmacist. CCGP will provide certificants with a certificate of recognition suitable for framing. In addition, certificants will be entitled to additional items, such as lapel pins, that display the logo for Certified Geriatric Pharmacist. Contact CCGP for additional information.

QUESTIONS ABOUT THE EXAMINATION

Candidates may not have access to the examinations or to specific questions except during administration of the examination. Candidates may comment on any question, the administration of the examination or the test center facilities on their answer sheet on the day of the examination. Individual responses to question comments will not be provided.

DUPLICATE SCORE REPORTS

Requests for duplicate score reports must be made in writing to AMP within one year of the examination date. Your request must include your name, social security number, mailing address, examination date, test center and signature. The fee for a duplicate score report is \$25; be sure to include a check or money order made payable to AMP for this amount with your request.

CONTINUATION OF CERTIFICATION

All Certified Geriatric Pharmacists are required to maintain their certification, in good standing with the CCGP. To do so, certificants will be requested to submit an annual guestionnaire and a signed Attestation of a Valid License. Failure to submit a signed Attestation may jeopardize the certificant's good standing with CCGP, ultimately resulting in suspension of their certified standing.

RECERTIFICATION

Every five (5) years, certificants will be required to complete a recertification process. This process involves:

 paying the \$600 Recertification Application Fee and achieving a passing score on a multiple-choice objective examination, based on the content outline of the Certification Examination in Geriatric Pharmacy

OR

2) paying the \$600 Recertification Application Fee and successfully completing the Professional Development Program for CGP Recertification. Please visit the CCGP website for further information on this program at www.ccgp.org. Recertification is required to provide assurance that practitioners are maintaining their knowledge and skills in geriatric pharmacy practice.

RECERTIFICATION GRACE PERIOD

If a CCGP Certified Geriatric Pharmacist (CGP) fails to successfully complete the recertification process, extension of her/his certification may be granted for six months while he/she seeks to successfully complete the process. If a CCGP certified pharmacist does not complete the process within that period, then the individual's status as a CGP will lapse. Once certification has lapsed, reinstatement can be achieved only by successfully completing the entire certification process.

EXAMINATION CONTENT

To begin your preparation in an informed and organized manner, you should know what to expect from the actual examination in terms of the content. Information regarding the content of the examination is presented in this handbook. The content outline will give you a general impression of the examination and, with closer inspection, can give you specific study direction by revealing the relative importance given to each category on the examination.

Note: Medications on the certification examination will be referred to by the generic name only (USAN or USP name). Medications which are known by the British Approved Name outside the United States will have this name in parentheses. For example: albuterol (salbutamol). Laboratory examination results will be presented in both conventional and international units. The content for the examination is based on a job analysis and is described in the following detailed content outline.

			QUESTIONS				
Certified Geriatric Pharmacist Detailed Content Outline Percentages for minor content area are approximate, and based on the number of items in that section. Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.				TOTAL %			
. PATIENT SPECIFIC ACTIVITIES	12	25	15	35%			
A. Collect and Evaluate Patient-Specific Information	2	7	2	21%			
1. Interpret and apply knowledge of the following to the provision of pharmaceutical care for older adults:							
a. incidence of disease, comorbidity and disability			X ²				
b. patterns of medication use	1		Х				
c. causes of morbidity and mortality			Х				
Assess and apply understanding of the following issues to the provision of pharmaceutical care for older adults:							
a. continuum of care			X				
b. wellness and health promotion			Х				
c. loss of independence			Х				
d. end of life issues (advance directives, treatment issues, quality of life choices)			X				
e, ethical issues		<u> </u>		ļ			
Evaluate the social aspects of aging in the provision of pharmaceutical care for older adults related to the following:							
a. economic issues		ļ	Х				
b. availability of community based services (referrals and triage)			X				
c. isolation			Х				
d, losses			Х				
e. role of caregiver							
4. Communicate with elderly patients, their caregivers and healthcare professionals:							
 a. recognize communication barriers including age-related sensory and cognitive impairments, illiteracy, and language and cultural differences 		. X	X				
b. apply strategies to overcome communication barriers	ļ		X				
c. apply privacy and confidentiality principles		ļ	X				
d. ensure patient understanding of prescribed therapy							
Evaluate physiological changes that accompany aging (e.g., sensory, body composition, organ system function)			Х				
6. Interpret and monitor laboratory results and procedures for the older patient		ļ					
7. Evaluate and apply results of standardized assessment tools (MMSE, GDS, etc.)	ļ						
8. Recognize and assess altered disease state presentations in the elderly	<u> </u>	<u> </u>	X				
9. Recognize and assess altered psychological status in the elderly	<u> </u>		X	ļ			
 Identify and assess compliance/adherence issues affecting potential treatment plans (e.g., memory loss, sensory changes, hearing, cognition, patient beliefs, economics, and learning disabilities) 							
11. Obtain an accurate drug history including over the counter and alternative/complementary medications	-	X	X	ļ			
12. Obtain and/or evaluate relevant physical assessment information		_	X	 			
13. Apply principles of pharmacokinetic and pharmacodynamic changes associated with aging to the design							
of the pharmacotherapy regimen	3	3	10	31%			
B. Identify, Resolve and Prevent Medication Therapy – Related Problems	+ -	+ 3	10	3170			
Untreated or under-treated conditions	-	-	 	-			
2. Improper drug selection	-	 	<u> </u>	 			
Subtherapeutic or Supratherapeutic dosage A Compliance (Adherance issues)		+	 	 			
Compliance/Adherence issues: a. monitor patient's compliance/adherence with medications and apply strategies to educate the patient and the patient a			X				
and/or caregiver, and encourage compliance/adherence with therapy b. promote elder-appropriate drug labeling and packaging		-	 ^				

			QUESTIONS				
	Certified Geriatric Pharmacist Detailed Content Outline centages for minor content area are approximate, and based on the number of items in that section. aded "X" denotes that NO items should be written at the indicated cognitive level for the task.	Recall	Application	Analysis	TOTAL %		
	5. Adverse drug events		***************************************				
	6. Drug interactions						
	7. Drug use without indication						
	8. Treatment fallures						
C.	Determine Patient's Pharmaceutical and Related Health Care Needs and Integrate into Care Plan	0	1	2	6%		
D.	Select Drug Therapy Goals which Focus on Function and Quality of Life	√ 1	2	Х	6%		
E.	Design and Implement a Therapeutic Regimen in Collaboration with the Patient and Other Health Care Professionals	1	5	1	13%		
	Apply concept of risk: benefit for each drug				10 /0		
	Recommend non-prescription drugs			X			
	3. Educate patient on therapy options – generics, alternative therapies, nondrug therapies, formulary options, etc. Output Description drugs Output Des			X			
	Educate patient on medication-related problems (e.g., side effects of medication, drug interactions)			X			
	5. Recognize need for referral to specialized healthcare provider for further evaluation/treatment			X			
F.	Patient Monitoring Plan	5	7	0	23%		
- ' '	Design plan to monitor for safety, effectiveness and achievement of therapeutic goals		•	X			
	Implement plan			Х			
	Evaluate its effects on quality of life issues						
	Document steps and outcomes of pharmaceutical care plan		Χ	Χ			
		20	43	17	53%		
	EASE SPECIFIC ACTIVITIES	20	43	- 17	33 %		
Α.	Cardiovascular Disorders – e.g., Hypertension, Heart Failure, Ischemic Heart Disease, Myocardial Infarction, Cardiac Arrhythmias, Hyperlipidemia, Peripheral Vascular Disease	2	5	2	11%		
	Recognize common signs and symptoms		X	X			
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			Х			
	3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors						
	 Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary 						
В.	Dermatologic Disorders – e.g., Pressure Ulcers, Drug Induced Skin Disorders, Xerosis, Fungal Rashes, Other Common Skin Disorders	1	1	0	3%		
	Recognize common signs and symptoms		X	X			
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			X			
	3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors						
	Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary						
C.	Endocrine and Exocrine Disorders – e.g., Thyroid Disorders, Diabetes Mellitus, SIADH, Disorders of the Adrenal Gland, Paget's Disease, Hormone Replacement Therapy	2	4	2	10%		
	Recognize common signs and symptoms		Х	Х			
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			Х			
***************************************	Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors		1				
	Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary						

				QUESTIONS				
Certified Geriatric Pharmacist Detailed Content Outline 1 Percentages for minor content area are approximate, and based on the number of items in that section. 2 Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.			Application	Analysis	TOTAL %			
D.	Gastrointestinal Disorders- e.g., Peptic Ulcer Disease, Gastro-Esophageal Reflux Disease, Diarrhea and Constipation, Irritable Bowel Syndrome, Inflammatory Bowel Disease, Hepatic Disorder (Cirrhosis), Pancreatitis, Cholelithiasis	1	4	1	7%			
	 Recognize common signs and symptoms Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice 		Х	Х				
	guidelines, pharmocoeconomics, quality of life, patient satisfaction) 3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors	·		Х				
	Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary							
E.	Hematologic Disorders – e.g., Anemias, Disorders of Hemostasis, Thrombocytopenia, Disorders of White Blood Cells	1	2	1	5%			
	Recognize common signs and symptoms		X	X				
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			X				
	3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors							
	4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary							
F.	Infectious Diseases – e.g., Pneumonia, Urinary Tract Infection, Tuberculosis, Herpes Zoster, AIDS, Skin and Soft Tissue Infections, Hepatitis, Bone and Joint Infections, Genitourinary Tract Infection, Influenza, Ophthalmic Infections, Nosocomial Infections, Drug Resistance, Immunizations	2	3	2	9%			
	Recognize common signs and symptoms		Χ	Χ				
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			X	·			
-	Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors							
	Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary							
G.	Musculoskeletal Disorders – e.g., Osteoarthritis, Rheumatological Diseases, Osteoporosis, Gout, Acute and Chronic Pain, Foot Disorders	2	4	2	10%			
	Recognize common signs and symptoms		X	X	ļ			
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			Х				
	3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors							
	 Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary 							
Н.	Neurological Disorders – e.g., Cerebrovascular Disease (Stroke, Transient Ischemic Attacks), Movement Disorders (Parkinson's Disease, Essential Tremor), Dementias (Alzheimer's Disease, Lewy Body Disease, Ischemic Vascular Dementia), Delirium, Seizure Disorders, Neuropathies, Acute and Chronic Pain Syndromes	2	5	2	114			
	Recognize common signs and symptoms		X	X				
	Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice							
	guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	<u> </u>			
	Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors			ļ				
	 Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary 							

			QUES	TIONS	
Certified Geriatric Pharmacist Detailed Content Outline Percentages for minor content area are approximate, and based on the number of items in that section. Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.		Recall	Application	Analysis	TOTAL %
l.	Nutrition and Hydration Disorders – e.g., Malnutrition, Dehydration, Fluid and Electrolyte Disorders	1	2	1	5%
	Recognize common signs and symptoms		Х	Х	
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			Х	
	3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors	1			
	4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
	Oncology – e.g., Breast Cancer, Skin Cancer, Prostate Cancer, Lung Cancer, Colorectal Cancer, Brain Tumors	1	1	0	3%
	Recognize common signs and symptoms		Χ	Χ	
	2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			Χ	4
	3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
and the second s	4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
K.	Ophthalmology – e.g., Glaucoma, Dry Eyes, Blepharitis, Macular Degeneration, Cataracts	1	1,	0	3%
	Recognize common signs and symptoms		Х	Χ	
	2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
	3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors		·		
	 Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary 		•		
L.	Psychiatric Disorders – e.g., Depression and Other Mood Disorders, Schizophrenia and Other Psychotic Disorders, Sleep Disturbances, Anxiety Disorders, Behavioral Disorders, Alcohol and Drug Abuse	2	5	2	11%
	Recognize common signs and symptoms	<u> </u>	X	X	
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			X	
	3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
	4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
М.	Genitourinary Disorders – e.g., Urinary Incontinence, Benign Prostatic Hyperplasia, Sexual Dysfunction, Renal Failure	1	3	1	6%
	Recognize common signs and symptoms		X	Х	
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			Х	
	3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
	4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend				
	modifications in therapy as necessary				
N.	Respiratory Disorders – e.g., Chronic Obstructive Pulmonary Disease, Asthma	1	3	1	69
	Recognize common signs and symptoms	-	X	X	-
	 Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction) 			X	

	Cartified Cariatria Pharmaciat Datailed Contant Outline			QUE	STION	3
1 2		Certified Geriatric Pharmacist Detailed Content Outline recentages for minor content area are approximate, and based on the number of items in that section added "X" denotes that NO items should be written at the indicated cognitive level for the task.		Application	Analysis	TOTAL %
		3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other				
		 Evaluate drug response using effectiveness and safety endpoints, quality of life issues and remodifications in therapy as necessary 	ecommend			
III.	PO	PULATION SPECIFIC ACTIVITIES	5	5	8	12%
	A.	Research	_ 1	1	4	33%
	·-···	Conduct drug use evaluations (DUE) and drug use review (DUR)	Į.		X	
		2. Apply DUE/DUR results to improve the quality of care			X	
		3. Evaluate and apply research pertinent to the elderly				
		4. Interpret and apply geriatric practice guidelines				
	В.	Economics and Access	1	1	3	28%
		Develop and implement formulary management/protocols	-			
		2. Interpret pharmacoeconomic data			X	
		3. Develop and implement practice guidelines	-			
		4. Evaluate costs/benefits issues that influence access to medications or therapy for specific pa	atients			
	C.	Health Policy	3	3	1	39%
7, 1	41	Communicate with healthcare professionals to improve quality of care			X	
		2. Ensure that privacy and confidentiality standards are maintained		X	X	
	,	Optimize the Continuum of Care process				
		TOTAL	TEST 37	73	40	100%

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SAMPLE QUESTIONS

- 1. Which of the following is a common adverse effect of pentoxifylline?
 - A. letharay
 - B. dyspepsia
 - C. constipation
 - D. hypertension
- 2. Which of the following drugs is most likely to contribute to falls in an elderly patient?
 - A. aspirin
 - B. alenodronate
 - C. prazosin HCI
 - D. cefadroxil monohydrate
- 3. Which of the following should be included in the documentation of a pharmaceutical care plan?
 - 1. the decision-making process that has been used
 - 2. any interventions that have been made
 - 3. a description of patient-specific outcomes
 - A. 1 and 2 only
 - B. 1 and 3 only
 - C. 2 and 3 only
 - D. 1, 2, and 3
- 4. Which of the following is the recommended daily intake of elemental calcium for postmenopausal women, who are not taking hormone replacement therapy?
 - A. 500 mg
 - B. 1000 mg
 - C. 1500 mg
 - D. 2000 mg
- 5. An elderly man with diabetes mellitus presents with cellulitis of the lower right leg. The patient is started on cephalexin HCl 500 mg po q6h with no significant improvement after 5 days of treatment. Which of the following is the most appropriate antibiotic for this patient?
 - A. cefixime
 - B. ciprofloxacin
 - C. co-trimoxazole
 - D. amoxicillin/clavulanate potassium

Answer Key:

1. B 2. C 3. D 4. C 5. D

SELF-ASSESSMENT EXAMINATION

CCGP offers a Self-Assessment Examination (SAE) to help candidates prepare for the Certification Examination in Geriatric Pharmacy. The SAE is available in an online, Web-based format and in paper-and-pencil, booklet format.

WHO SHOULD USE THE SELF-ASSESSMENT EXAMINATION?

- 1. Candidates Evaluate your readiness for taking the proctored certification examination.
- 2. Employers Measure your employees' knowledge and skills in geriatric pharmacy practice.
- 3. Pharmacists Assess your knowledge and skills in geriatric pharmacy practice.
- 4. Students Identify weak areas before completing educational programs to better prepare for licensing examinations.

The SAE consists of 150 multiple-choice questions based on the current Certification Examination content outline. Candidates completing the SAE will receive total scores and a summary of strengths and weaknesses by content area. Both versions of the SAE (Web-based and paper-and-pencil) contain explanations for each correct and incorrect answer, helping you to better understand the reasoning that supports the correct therapy. In addition, the SAEs contain an up-to-date reference list of books and journals that focus on geriatric pharmacotherapy!

For more information about the Web-based SAE, please visit www.ccgp.org and click on the link "Self Assessment Program." To order a copy of the paper-and-pencil SAE, complete the order form in the back of this handbook.

RECOMMENDED REFERENCES

The CCGP Examination Development Committee recommends the following references as useful in learning the basics of geriatric pharmacy practice. This list does not attempt to include all acceptable references, nor is it suggested that the Certification Examination in Geriatric Pharmacy is necessarily based on these references. You should obtain the most current edition available.

General Pharmacotherapy

Applied Therapeutics: The Clinical Use of Drugs. Koda-Kimble MA and Young LY.

Pharmacotherapy: A Pathophysiologic Approach. DiPiro JT, et. al.

Geriatrics

Essentials of Clinical Geriatrics. Kane RL, Ouslander JG, and Abrass IB. New York: McGraw-Hill. ISBN 0-07-033473-0. Available from ASCP. Order phone 800/355-2727. \$36.

Merck Manual of Geriatrics. Abrams WB, Beers MH, et.al., eds. Whitehouse Station: Merck and Company. ISBN 0-911910-66-2. Order phone 800/659-6598. \$25.

Principles of Geriatric Medicine and Gerontology. Hazzard WR, et.al., eds. ISBN 0-07-027501-7. Available from ASCP, order phone 800/355-2727. \$142.50.

Practice Guidelines

The federal Agency for Healthcare Research and Quality (AHRQ) has practice guidelines on pertinent topics, such as heart failure and pressure sores. You may contact-AHRQ at 800/358-9295, or on the web at www.ahrq.gov.

The National Guideline Clearinghouse is a web site sponsored by AHRQ that contains hundreds of practice guidelines developed by a wide variety of organizations. This web site is located at www.guideline.gov.

Certification Examination in Geriatric Pharmacy EXAMINATION APPLICATION

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	REAPPLICANT: The last time I attempt Certification Examination in Geriatric F	Pharmacy was:		☐ Discover ☐ American Express
	RECERTIFICATION Candidate:	. 3 3 3 7		Account No.
	☐ By Examination ☐ By Continuin	g Education		E L. R. M. W.
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	(if taken within two years)	\$300		Signature
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	nature:	•		Date:
OIF	ji lataro.			

Complete this form and submit it to Candidate Services, CCGP, 1321 Duke Street, Alexandria, VA 22314-3563 with the required fee.



REQUEST FOR SPECIAL EXAMINATION ACCOMMODATIONS

If you have a disability covered by the Americans with Disabilities Act, please complete this form and the Documentation of Disability-related Needs on the reverse side so your accommodations for testing can be processed efficiently. The information you provide and any documentation regarding your disability and your need for accommodation in testing will be treated with strict confidentiality.

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ipecial Accommodations		
request special accommodations for the examination(s).	Month / Year administration of the	
Reader Circle answers in Extended testing	n examination booklet g time (time and a half)	
Comments:		
Signed:		Date:



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Please have this section completed by an appropriate professional (education professional, doctor, psychologist, psychiatrist) to ensure that AMP is able to provide the required examination accommodations.

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Examination Applicant		Dale			
Professional Title					
The applicant discussed with me the nature of the examination adm disability described below, he/she should be accommodated by p side.	inistered. It is my providing the spe	y opinion that be ecial arrangemer	cause of this applicant's its listed on the reverse		
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Signed:		Title:			
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If you have questions, call the Candidate Services Department at 703/535-3036.



Price

PAPER-AND-PENCIL SELF-ASSESSMENT EXAMINATION ORDER FORM

CCGP offers a Self-Assessment Examination (SAE) to help pharmacists assess their knowledge and skills in geriatric pharmacy practice and help candidates prepare for the Certification Examination in Geriatric Pharmacy. The SAE is available in an online, Web-based format and in paper-and-pencil, booklet format. For more information about the Web-based SAE, please visit www.ccgp.org and click on the link "Self Assessment Program." To order a copy of the paper-and-pencil SAE, please complete this form and fax with payment to CCGP at 703/739-1500.

The SAE consists of 150 multiple-choice questions, is self-scoring, and is based on the current certification examination content outline. Candidates receive total scores and a summary of strengths and weaknesses by content area. The SAE also contains explanations for each correct and incorrect answer helping you to better understand the reasoning that supports the correct therapy.

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Date: November 29, 2006

Memorandum

To: Licensing Committee

From: Board of Pharmacy

Subject: Emergency Preparedness for California

At the October Board Meeting, the board amended and approved a general policy statement that outlines its expectations for how disaster response in California may proceed.

Over the coming months, the board will work with the Department of Health Services to provide responses to their questions. The goal of the board and the DHS is to assure that concerns can be addressed at the front end, and licensees and the public will have better knowledge of what the board will require, and be willing and comfortable volunteering to participate in emergency response.

Legislation or regulation changes may be an outcome of these discussions.

The modified disaster response policy follows on the next page.

Disaster Response Policy Statement

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. Skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at www.medicalvolunteer.ca.gov (California) and www.medicalvolunteer.ca.gov (California) and www.medicalreservecorps.gov (federal). The board also continues to be actively involved in such planning efforts, at every level.

The board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected. The board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

¹ Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

Furthermore, during a declared disaster or emergency affecting residents of California, the board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California.² The board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California. Finally, the board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

² See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states.

Memorandum

To: Licensing Committee

Date: November 27, 2006

From:

Board of Pharmacy

Subject: National Provider Identifier (NPI)

FOR INFORMATION:

One component of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) required that the Health and Human Services Agency adopt a unique health identifier for health care providers. On January 23, 2004, the government published the final rule creating the National Provider Identifier (NPI) as the identifier.

All HIPAA-covered providers, whether they are individuals or companies, must obtain an NPI for use in HIPAA covered, HIPAA standard transactions (e.g., NCPDP for retail prescription drugs). This affects pharmacists and pharmacies, all of whom will need to obtain an NPI. Once issued, a provider's NPI will not change, even if a pharmacist's job or pharmacy location changes.

HIPAA-covered entities must use only the NPI to identify covered health care providers in standard transaction by May 23, 2007.

Pharmacists and pharmacies can obtain this number from CMS.

Materials regarding the NPI are contacted in this tab section.







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National Provider Identifier Standard (NPI)

Overview

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Overview

Only 188 more days until the National Provider Identifier (NPI) compliance date! Do you have your NPI?

Transcript for 9/26/06 NPI Roundtable Now Available

The complete transcript for the 9/26/06 NPI Roundtable is now available – click on "Educational Resources" to the left of your screen to view this document.

NPI Tip

When applying for your NPI, CMS urges you to include your legacy identifiers, not only for Medicare but for all payors. If reporting a Medicaid number, include the associated State name. This information is critical for payors in the development of crosswalks to aid in the transition to the NPI.

View a letter (located in the Downloads section below) from CMS Administrator, Dr. Mark B. McClellan, announcing the start of NPI enumeration for all health care providers.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated that the Secretary of Health and Human Services adopt a standard unique health identifier for health care providers. On January 23, 2004, the Secretary published a Final Rule that adopted the National Provider Identifier (NPI) as this identifier.

All HIPAA covered healthcare providers, whether they are individuals or organizations, must obtain an NPI for use to identify themselves in HIPAA standard transactions. Once enumerated, a provider's NPI will not change. The NPI remains with the provider regardless of job or location changes.

HIPAA covered entities such as providers completing electronic transactions, healthcare clearinghouses, and large health plans, must

use only the NPI to identify covered healthcare providers in standard transactions by May 23, 2007. Small health plans must use only the NPI by May 23, 2008.

Downloads

NPI Final Rule [PDF, 249KB]

Dear Provider Letter from CMS Administrator [PDF, 125KB]

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HIPAA - General Information

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There are no Related Links Outside CMS

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National Council for Presiment Drug Programs NCPDP

FAQs on NPI Enumeration

What is an NPI? (revised 7/1/06)

The National Provider Identifier (NPI) is the provider identifier, replacing the different provider identifiers pharmacies currently use including the NCPDP Provider ID number (formerly the NABP number). This identifier, which implements a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), must be used by most HIPAA covered entities, which are health plans, health care clearinghouses, and health care providers that conduct electronic transactions for which the Secretary has adopted a standard (i.e., standard transactions). Health care providers include individuals, such as physicians, dentists, and pharmacists, and organizations, such as hospitals, nursing homes, pharmacies, and group practices. The use of the number on HIPAA transactions is mandatory by May 23, 2007 for most health plans (2008 for can be found More information plans). small http://www.cms.hhs.gov/apps/npi/01_overview.asp

How do pharmacies obtain their NPI? (revised 7/1/06)

Pharmacies are able to apply for their NPI in one of three ways:

- (1) With their permission, NCPDP will submit their application in an electronic file and provide the pharmacy's NPI to them. NCPDP recommends this option as a service to the industry. This authorization process is underway and the NCPDP bulk enumeration process has begun. Go to http://www.ncpdp.org/frame_news_npi-info.htm
- (2) Pharmacies may prepare a paper application and send it to the entity that will be assigning the NPI on behalf of the Secretary (the Enumerator). A copy of the application, including the Enumerator's mailing address, is available on at http://www.cms.hhs.gov/NationalProvIdentStand/03 apply.asp#TopOfPage Pharmacies may also call the Enumerator for a copy. The phone number is 1-800-465-3203 or TTY 1-800-692-2326.
- (3) Pharmacies may apply through a web-based application process. The web address is the same as #2 above.

What is the NPPES? (revised 7/1/06)

NPPES is the National Plan and Provider Enumeration System. CMS and the Enumerator, Fox Systems, Inc., use this system to enumerate and maintain information on all providers who apply for an NPI or submit changed information. The NPPES does not have the capability to link a group of pharmacies together into a chain or other affiliations. In addition, it is not currently known if, how, or when CMS will disseminate NPI numbers to industry. For this reason, it is important that the industry continue to use the NCPDP Pharmacy Database, which will include a pharmacy's new NPI(s) crosswalked to their NCPDP Provider ID to avoid industry disruption in converting from the NCPDP Provider ID to the NPI.

What is an "EFI Organization"? (revised 7/1/06)



An EFI Organization (EFIO) is a term used by CMS to describe an entity that has been certified by CMS to serve as an authorizing provider's agent in submitting an electronic NPI application for the provider and to distribute the NPI to the provider(s). EFIOs may also submit changes to provider data such as address and maintain provider data in the NPPES. EFIOs are certified by CMS through their Enumerator before they are able to perform these functions. There is no other way to batch enumerate a group of pharmacies. All other NPI enumeration methods (web and paper) require individual applications, one-by-one, and require one-by-one updates.

NCPDP is a certified EFIO and recommends pharmacies obtain their NPIs by authorizing NCPDP as their EFIO. This will insure data are correct on the NPPES as well as on the NCPDP Pharmacy Database available to industry.

Do all pharmacies need an NPI?

All pharmacies that submit HIPAA covered transactions must obtain and use an NPI by May 23, 2007. NCPDP recommends all pharmacies obtain an NPI, even if HIPAA covered transactions are not used by the pharmacy.

Has CMS approved NCPDP to be an EFIO? (revised 7/1/06)

Yes. NCPDP is certified to submit records for enumeration on behalf of pharmacies with their authorization. In May, NCPDP submitted smaller files and streamlined business processes in the live environment. NCPDP has steadily increased the number of files submitted weekly as well as the size of those files. NCPDP is currently accepting updated information and authorizations from pharmacies. With the exception of new pharmacies and change of ownerships, pharmacies are enumerated in the order in which their updated information is received, allowing for CMS file size and frequency restrictions. New pharmacies and Change of Ownership situations take priority.

Why should a pharmacy use NCPDP as an EFIO to obtain NPIs? (revised 7/1/06)

NCPDP has been successfully enumerating pharmacies since 1981 during which time NCPDP has provided pharmacies with NCPDP Provider ID numbers (formerly known as NABP numbers). In addition to enumeration, NCPDP maintains the NCPDP Pharmacy Database, which is purchased by industry for many uses including claims processing, product recalls, publications, network development and health plan directories. Using NCPDP to obtain NPIs will insure pharmacy information is current on the NCPDP Pharmacy Database, result in minimal industry disruption and aid in proper claims reimbursement.

If a pharmacy is owned or are affiliated with a group of pharmacies, there is no other way of applying for NPIs other than a single web-based or paper application per pharmacy. Enumerating a large group of pharmacies can result in significant administrative burden associated with gathering, formatting, editing, validating, applying over the web (which CMS states takes 20 minutes per number) and maintaining data in NPPES.



Will NCPDP discontinue issuing NCPDP Provider (formerly NABP) ID numbers? (revised 7/1/06)

No, NCPDP will continue to issue NCPDP ID numbers, even if they are not used on a HIPAA standard transaction. NCPDP expects Workers Compensation and other programs not covered by HIPAA will continue to use NCPDP Provider ID numbers for some time into the future. It is expected that many processors will crosswalk the NPI to the NCPDP Provider ID and will continue to use the NCPDP ID for processing in the near to intermediate term. The relationship and demographic information found on the NCPDP Database files is needed more than ever by the industry. NCPDP will continue issuing NCPDP Provider ID numbers - even if the only future use is internal to NCPDP and users of our database. There are no plans to phase out the numbers.

So, NCPDP is going to continue to assign NCPDP numbers even after NPI is fully operational? If so, for how long? (revised 7/1/06)

Yes. Industry is continuing to use NCPDP ID numbers on claims until May 23, 2007 and after that date, most claims processors if not all will simply convert the NPI to the NCPDP ID before processing. NCPDP has committed to industry that there will be a one-to-one relationship between NCPDP Provider ID numbers and NPIs so that industry can easily develop crosswalks between the NPI and the NCPDP Provider ID number for information and claims processing systems. NCPDP will perform this service indefinitely.

How can NCPDP do all the work necessary for EFI submission at no additional cost to pharmacies?

NCPDP can do all the work required at no additional cost to pharmacies just like they do today in maintaining the NCPDP Pharmacy Database. NCPDP sells this database to the industry to recoup its pharmacy NPI enumeration costs. NCPDP, with a pharmacy's authorization and the required information on an NCPDP-developed Application Form or Excel format, will obtain pharmacy NPI(s) and maintain NPIs (i.e. maintaining the CMS National Plan and Provider Enumeration System, NPPES) for authorizing pharmacies as required by Federal Law. NCPDP agrees that all this work will be done at no additional cost to pharmacies. The only cost involved is the current cost of \$100 for enumerating new pharmacies or those that change ownership.

What are the advantages of using NCPDP as an EFIO? (revised 7/1/06)

If a pharmacy is owned or are affiliated with a group of pharmacies, there is no other way of applying for NPIs other than becoming an EFIO or applying for each pharmacy using an individual web-based or paper application. Enumerating a large group of pharmacies can result in significant administrative burden gathering, formatting, editing, validating, and maintaining data in addition to filling applications and correcting errors.

Pharmacies benefit from the various industry uses of NCPDP's Pharmacy Database information. Specifically, entities within the pharmacy industry use this pharmacy



information for affiliating pharmacies with their respective chain headquarters or networks, claims processing, direct mailings of product recalls and publications, network development, health plan directories and rebate information. NCPDP, functioning as an EFIO provides pharmacies with a single method of maintaining pharmacy information in this important industry database as well as the NPPES, which does not contain all the information needed by industry to process claims.

NCPDP's Pharmacy Database contains pharmacy NPI(s) as well as legacy NCPDP Provider ID numbers (formerly the NABP number). This provides industry with the much-needed crosswalk between the two IDs and minimizes industry disruption or errors in claims payment.

What entities other than pharmacies will NCPDP enumerate?

There are some entities or non-pharmacy dispensing sites that dispense medication under the supervision of a physician such as certain clinics, emergency rooms or dispensing physicians. NCPDP can enumerate those non-pharmacy dispensing organizations (not the physician) in addition to pharmacies.

Will NCPDP also enumerate pharmacists?

No. NCPDP is only enumerating pharmacies, non-pharmacy dispensing sites and certain DME providers. If a pharmacist *bills* for medication therapy management or other professional pharmacy services or conducts any other HIPAA standard transactions, pharmacists must obtain an individual NPI.

Will this allow my pharmacist to be paid directly for their services?

In some cases, it will be the pharmacy that is to be paid for the pharmacist's medication therapy management or professional services. In that case, the NPI of the pharmacy is the biller, (NCPDP Service Provider ID on the Telecommunication Standard Version 5.1 Claim) and the NPI of the pharmacist is the rendering provider (Pharmacy Provider Segment on the Version 5.1 Claim).

What was the purpose of the pledge pharmacies were asked to sign last year on behalf of our affiliated pharmacies? (revised 7/1/06)

The pledge NCPDP requested from organizations representing various groups of pharmacies in late 2005 was to determine industry interest in NCPDP becoming an EFIO and to help NCPDP size the level of effort NCPDP would have enumerating pharmacies. The pledge also insured organizations received regular communication regarding the status of the enumeration. Now that NCPDP is an authorized EFIO, the pledge has no importance. It is important now that pharmacies *authorize NCPDP to be their EFIO*. This can be done by updating pharmacy data with NCPDP using the NCPDP Application/Update Form, Checking the box and signing Section 11 of the Application. The Form can be found at http://www.ncpdp.org/frame_news_npi-info.htm. If the organization is a larger chain, an Excel Template is available and an Authorization



Letter. This information is also available at http://www.ncpdp.org/frame_news_npi-info.htm.

What do pharmacies do to authorize NCPDP to be their EFIO in obtaining NPIs? (revised 7/1/06)

NCPDP has emailed all those that have submitted pledges and asked for authorization. There is also a link to the NCPDP website where individual pharmacies can download a form to fill out the necessary information and authorize NCPDP. The link is http://www.ncpdp.org/frame_news_npi-info.htm. The form can be faxed or mailed to NCPDP.

If an organization owns many pharmacies, an Excel file template and Chain Authorization Letter is available at the same site.

Our chain has more than one relationship or chain code. Do we need to fill out one Excel Template for each chain code? (revised 7/1/06)

Yes. NCPDP needs one spreadsheet for each chain code. This is because NCPDP sets permission flags for authorization to enumerate based on chain codes and NCPDP submits batches or files to NPPES for chains based on chain code.

What are the pharmacy's responsibilities in order for NCPDP to enumerate? (revised 7/1/06)

Federal Law requires the information sent to NPPES to enumerate a pharmacy be correct. The pharmacy's responsibility is to verify NCPDP has the correct information on the pharmacy. The best way to do this is to go to http://www.ncpdp.org/frame_news_npi-info.htm and send NCPDP the updated Application and indicate the pharmacy is updating pharmacy information and authorizing NCPDP to be an EFIO.

NCPDP is updating information on the NCPDP Pharmacy Database based upon these Applications and Excel spreadsheets to insure pharmacy information is current prior to enumeration of authorizing pharmacies. If the pharmacy has not authorized NCPDP to enumerate the pharmacy NCPDP will not enumerate the pharmacy until the pharmacy does so.

Why is NCPDP asking pharmacies to maintain more information than that needed for getting an NPI?

NCPDP can do all the work required to obtain pharmacy NPI(s) and maintain the NPPES at no additional cost to pharmacy because NCPDP sells the NCPDP Pharmacy Database to industry to recoup its pharmacy NPI enumeration and maintenance costs. The NCPDP Pharmacy Database contains more information than that required by NPPES and has been licensed to industry for over 20 years.

Updated: 7/1/06



Pharmacies benefit from the various industry uses of NCPDP's Pharmacy Database information. Specifically, the entities within the pharmacy industry use this pharmacy information for different business reasons. For example, for affiliating pharmacies with their respective networks or chain headquarters, claims processing, direct mailings of product recalls and publications, network development, health plan directories and rebate information. This information will not be available top industry from NPPES.

How will NCPDP determine which pharmacies to enumerate first? (revised 7/1/06)

NCPDP has worked with CMS and the Enumerator, Fox Systems, Inc. to develop an enumeration plan for pharmacies. NCPDP was asked to submit small files initially and until all processes are tested. Non-chain pharmacies, new pharmacies, and resubmission of rejected records are sent on weekly files to the NPPES system for enumeration. Chain pharmacies are enumerated in batches corresponding with primary relationship codes or "chain codes". Any record issues are triaged between NCPDP, the Enumerator and the pharmacy contact person on the Application.

Effective May 1, 2006, before the NSC can process any Medicare Supplier ID enrollment documentation or make any updates to a supplier file, the supplier must ensure their NPI has been listed on the CMS-855S application. How does this impact NCPDP/s ability to enumerate pharmacies? (revised 7/1/06)

NCPDP has changed our processes so that new pharmacies and pharmacies who change ownership will receive priority when NCPDP submits records to NPPES for NPI enumeration. NCPDP then provides non-chain pharmacies with an email containing the pharmacy NPI to attach to the CMS-855S application. For chain pharmacies, written notification is provided to satisfy this Medicare requirement. For more information on the NPI and CMS-855S applications, please contact Jeannine Deese at ideese@ncpdp.org. It is expected the need for a paper copy of the NPI notification will not be necessary after NPPES dissemination is functional.

What happens if NPPES rejects some of the information submitted by NCPDP? (revised 7/1/06)

If the NPPES system <u>rejects</u> information submitted by NCPDP such as invalid zip code, phone number or address or a potential duplicate submission, NCPDP attempts to correct the error and resubmit the application. NCPDP contacts the individual authorized as the pharmacy "contact person" if NCPDP requires aid in resolving the rejected or pended application record. The most common reason for rejection of independent pharmacy records is "potential duplicate". This means that although the pharmacy gave NCPDP permission to be their EFIO, pharmacies may have already enumerated themselves and the rejection is sent to NCPDP. <u>If NCPDP calls a pharmacy to verify information and clear the pended or rejected record with CMS, it is very important and required by law that the pharmacy aid NCPDP in resolving the matter on a timely basis. This also insures the NCPDP Pharmacy Database is correct and the pharmacy's NPI is on file to avoid payment disruption.</u>



If NPPES <u>pends</u> the information on a record for Enumerator review, then the Enumerator contacts NCPDP or the pharmacy to receive clarification, if necessary and either accepts or rejects the record. If rejected, the record can be corrected and resubmitted.

If NPPES rejects an <u>entire NCPDP submission</u> on behalf of a chain or other affiliate because it contains an unusual number of errors, NCPDP retains the right to request that chain or affiliate resolve the errors and resubmit a file to NCPDP. Pharmacies are responsible for the quality and validity of the information provided.

How important is it that NCPDP has current information on pharmacies? (revised 7/1/06)

Federal Law requires that pharmacies certify the information submitted to NPPES is correct and that changes are sent to NPPES within 30 days of a change. For this reason, NCPDP is requesting pharmacies fill out the form at http://www.ncpdp.org/frame_news_npi-info.htm and update NCPDP within 20 days of a change of information. The Form provides a method for individual pharmacies to certify the information is correct. NCPDP will also require those sending the Excel Template file to certify the information sent to NCPDP is correct.

Our organization has downloaded the Excel Template. Can we just cut and paste from other lists or spreadsheets to provide the information NCPDP needs? (revised 7/1/06)

Yes. As long as all periods, apostrophes, dashes, ampersands & # symbols are removed. Make sure these characters are removed from the legal business name, dba name, physical address1, contact name, cross streets, mailing address 1 &2, mailing city, and state license fields. Follow the instructions carefully to avoid the need for more clean-up. NCPDP suggests a sample file with a dozen records or so are sent for review prior to an entire Excel File

What is the process once files are sent to NPPES and the Enumerator? How soon will our organization receive our NPI(s) (revised 7/1/06)

NPPES sends a response file 6 days after NCPDP sends the submission file. Records on the response file can either be enumerated, rejected or pended to the Enumerator. NCPDP researches and resubmits rejected records. This sometimes requires calling the pharmacy and working with the pharmacy to resolve the problem. The Enumerator resolves pended records. The Enumerator contacts NCPDP and/or the pharmacy contact person to aid in resolution. Pended records that have been finalized are sent on another file 6 days later. It is very important as a Federal requirement that pharmacies respond to calls from NCPDP or the Enumerator to resolve these pended records.

Remember, the 6-day turnaround time is for the NPPES first and all future response files as a result of the original submission. NCPDP notifies pharmacies of their NPI on enumerated records. In the case of independents, an email is sent. From NPI EFIO@ncpdp.org. In the case of chains, an email and file of NPIs is sent once all pharmacies are enumerated. Keep this email as some payers or processors may

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require a copy including Medicare when enrolling/changing information related to the Medicare Supplier ID.

How are pharmacies notified of their NPI(s)? (revised 7/1/06)

After obtaining a file's NPIs, NCPDP notifies pharmacies (or chain headquarters of the pharmacy if it is part of a chain) of their NPI(s) via email. Please watch for an email from NPI EFIO@ncpdp.org. NCPDP plans to have all authorizing pharmacies enumerated by late fall 2006 and will then begin outreach to pharmacies for which no NPI is on file. If a pharmacy is late in sending information to NCPDP, the pharmacy will be enumerated later. Enumeration is an ongoing process and will not cease. The NPI must be used on all HIPAA transactions by May 23, 2007. Therefore, NCPDP and its members recommend all pharmacies obtain NPIs by December 2006. Industry needs adequate time for testing prior to May 2007.

After getting NPIs from NCPDP, what are a pharmacy's responsibilities in the future?

Over time, information on pharmacies may change. It is the pharmacy's or chain headquarter's responsibility to notify NCPDP of changes as soon as possible so that NCPDP can update NPPES within 30 days as required by Federal law.

How often should a pharmacy update information with NCPDP?

NCPDP recommends pharmacies submit an update form to NCPDP or an updated file within 10 days of a change in information or annually if information has not changed.

Our pharmacy already has an NPI. What do we do?

If a pharmacy already has an NPI, pharmacies can still authorize NCPDP to maintain data in NPPES for them. Simply fill out the NCPDP Application Form on the NCPDP website at http://www.ncpdp.org/frame_news_npi-info.htm, provide the NPI in the proper space, check the authorization box in Section 11 and sign the NPI authorization line. If a pharmacy wished to maintain NPPES information itself, but wants to insure information and NPI on the NCPDP Pharmacy Database are correct, fill out the same form, provide the NPI on the application, do not check the authorization box or sign the NPI authorization line, and send or fax the application form to NCPDP.

If one of our group of pharmacies has already applied (separately) and received an NPI, will the one that NCPDP gives us when the EFIO enumeration occurs replace that NPI? What if we don't know that a pharmacy has already obtained a number? (revised 7/1/06)

If a pharmacy already has an NPI and NCPDP does not have the number on our database, NCPDP will attempt to submit for an NPI on behalf of that pharmacy. The NPPES system will pend or deny the record as a potential or exact duplicate. If a chain or group of pharmacies is aware of NPIs for some in the group, please provide them to

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NCPDP to avoid this situation. If not, after some research, the actual NPI of the pharmacy will be determined and the duplicate record will be denied in NPPES.

If our organization authorizes NCPDP to be our EFIO, must we also use NCPDP for ongoing maintenance?

Pharmacies can notify NCPDP if they wish to rescind authorization. NCPDP contacts the Enumerator, Fox Systems, Inc. who provides pharmacies with a log-on ID and password for the NPI website for each pharmacy that wishes to maintain their own information after previously authorizing NCPDP. If this option is chosen, NCPDP asks that the pharmacy maintain information with NCPDP as in the past so that the Database reflects accurate information.

CMS requires that the pharmacy notify NPPES within 30 days of a change of address or other information. The easiest way to do this is to notify NCPDP using the proper form on the NCPDP website. NCPDP will update the NCPDP Pharmacy Database and update NPPES (CMS).

What is a taxonomy code and where will we find them? (revised 7/1/06)

Taxonomy codes describe the type and specialty of providers. A minimum of one taxonomy code is required for obtaining an NPI. The NCPDP Pharmacy Database has been modified to carry up to 15 taxonomy codes per pharmacy. This is an example of additional information NCPDP needs from pharmacies prior to enumerating a pharmacy.

Taxonomy codes are codes maintained by the National Uniform Claim Committee (NUCC) to describe provider types and specialties. There are currently twelve (12) taxonomy codes for pharmacies as well as other specialties such as DME. They are listed at www.wpc-edi.com/taxonomy. If a pharmacy applies for their own NPI, pharmacies will need to include these code(s) on the NPI application. If NCPDP is applying for a pharmacy's NPI on their behalf, check the appropriate pharmacy taxonomy codes on the NCPDP application form.

Can a pharmacy have multiple NCPDP numbers? For example, if pharmacies are performing multiple services (LTC vs. Retail vs. Home Infusion), could a pharmacy have an NCPDP number and NPI for each? Moreover, would it depend on what types/numbers of state licenses or taxonomies that the pharmacy has? (revised 7/1/06)

Although NCPDP has always had a policy of one NCPDP Provider ID for each pharmacy and that has generally worked in the past, the NPI Final Rule does allow organizational providers to have more than one NPI. This does not apply to individuals or sole proprietorships. The most frequent example of this will be an NPI for the pharmacy and a separate NPI for DME. With the exception of DME, NCPDP discourages the use of multiple NPIs for a pharmacy as it goes against administrative simplification and often there are other attributes of a standard claim that can indicate whether the pharmacy is performing services as community/retail, long term care or a home infusion pharmacy. If



a pharmacy is unsure of what to do, contact jdeese@ncpdp.org and NCPDP will work with the pharmacy to determine the best coarse of action.

Our pharmacy also sells DME supplies. Do we need a second NPI? (revised 7/1/06)

No. Medicare requires providers have a separate DME NPI for each location. However, the DME NPI can be the same as that location's pharmacy NPI. This is the provider's choice. Please include the appropriate taxonomy code(s) on the application. Taxonomies are maintained in the NCPDP Pharmacy Database and submitted to NPPES. If, a pharmacy currently has two NCPDP Provider ID numbers for business reasons (one for pharmacy and one for DME), NCPDP recommends pharmacies obtain a second NPI corresponding with the second NCPDP Provider ID number and include the appropriate taxonomy under each number.

Our pharmacy currently has two NCPDP ID numbers for different operations. Do we need two NPIs? (updated 3/2/06)

No. However, if a pharmacy currently has two NCPDP ID numbers, NCPDP recommends the pharmacy apply for two NPIs. Pharmacies are organizations and organizations can have more than one NPI for their respective "subparts".

There is a chance NPPES will reject or pend the second application as a possible duplicate. NCPDP will work with the Enumerator, Fox Systems, that the pharmacy or pharmacy headquarters to allow the second NPI. Make sure the Taxonomy Code/Business Type section on the application is different for each application to describe the respective business subpart operation.

Industry has developed taxonomy codes (including LTC) so pharmacies can more clearly describe the services pharmacies perform. They are on the NCPDP application. Additional codes are available at http://www.wpc-edi.com/taxonomy.

Does the NCPDP Database design allow for more than one NCPDP number to be linked to the same NPI; or will it allow different NCPDP numbers to be linked to the same NPI at different times? (revised 7/1/06)

No. Only one NPI can be assigned to each NCPDP Provider ID and only one NCPDP Provider ID is assigned to any given NPI. If an NPI or NCPDP Provider ID is deactivated due to a store closing or change in ownership, the corresponding number is deactivated as well. In the case of a change in ownership, it is the decision of the sellers and buyers whether the buyer will retain the seller's NCPDP ID and NPI. If the buyer is to retain the seller's identifiers, the seller must provide NCPDP with written and notarized permission that the buyer can retain the identifiers. The transaction is reflected on the next monthly file sent to subscribers. A given NCPDP Provider ID and NPI are always linked; although EINs, relationship codes and other information related to those numbers may change.

Does a change in ownership require a change in NCPDP numbers? (revised 7/1/06)



Current rules will continue to be effective. A change in ownership does not require a change in identifiers. Whether or not there is a change of identifiers is a condition of the sale. The seller must notify NCPDP if the buyer is to retain the identifiers and the notification must be notarized. If an NPI is to be deactivated, only the pharmacy or chain headquarters is authorized by CMS to do so.

What if a pharmacy deactivates their NCPDP ID and NPI and later needs to reinstate the numbers? (revised 7/1/06)

I the past, NCPDP was able to re-instate a pharmacy with its original number relatively easily. This may not be the case with an NPI. It is not known at this time whether there is the ability to reinstate a deactivated NPI. Please contact NCPDP if the pharmacy encounters this situation and we will contact CMS to determine how best to solve the problem.

When should pharmacies begin using NPIs instead of NCPDP Provider ID Numbers? (updated 3/2/06)

The Workgroup on Electronic Data Interchange (WEDi) and NCPDP members have drafted a white paper that includes guidance for the industry and a timeline for the pharmacy industry for transition from the current NCPDP Provider Pharmacy ID to the NPI. Testing between pharmacies, processors and other trading partners will begin in late 2006. Certification testing and production use of the NPI is scheduled to begin in January 2007 with full transition to the NPI by May 23, 2007. After that date, the NPI must be used on all HIPAA covered transactions. The finalized white paper is available at www.wedi.org and on the NCPDP website at http://www.ncpdp.org/pdf/NPI_NCPDP_impact_on_phcy_services_sector_NCPDP_white_papers_2005-12-19.pdf. It also contains more detail on NPI implementation issues.

Does the NPI replace NCPDP Provider ID numbers on a HIPAA standard transaction such as a v5.1 claim?

Yes. Using the industry timeline, once a pharmacy's trading partners are "live", the NPI will replace the NCPDP ID on the HIPAA transaction. During the transition period in early 2007, it is possible that a pharmacy will need to submit the NCPDP ID on some claims to certain claims processors and the NPI to others. Please verify that your pharmacy system software is able to perform in this manner. Note that in addition to claims, the NPI will be used on standard HIPAA transactions including eligibility and prior authorization transactions. Note that this affects the real-time Telecommunication transactions, as well as the Batch Standard submissions.

When should pharmacies update data with NCPDP? (revised 7/1/06)

The time is now. Updating pharmacy information now will place the pharmacy in the enumeration queue maintained by NCPDP. After bulk enumeration, Federal Law requires that the NPPES be updated within 30 days of a change in information. NCPDP



encourages pharmacies to update NCPDP as soon as possible to insure the change meets the 30-day window. For pharmacy chains, NCPDP recommends chains provide NCPDP with one file that includes all updated information each month and another file with new stores to obtain NPIs

What should pharmacies be doing now to prepare for NCPDP's submission? (revised 7/1/06)

If the organization represents many pharmacies, NCPDP recommends obtaining the new standard NCPDP Excel™ Template at http://www.ncpdp.org/frame_news_npi-info.htm. Begin collecting the data needed from the appropriate sources and submit the file as soon as possible. An individuals pharmacy or small chain can download the new NCPDP Provider ID and NPI Application Form now at http://www.ncpdp.org/frame_news_npi-info.htm and submit data to NCPDP so that data is current.

When gathering information for the application, double check to insure that all information, such as demographic information, phone, fax, Taxonomy/Business Types, DEA, Medicaid, Medicare, Federal Employer Identification Numbers, are correct. This will reduce rejected applications and aid in resolving any potential duplicate issues.

Now that NCPDP is live and enumerating pharmacies, when will NCPDP add the NPI to the NCPDP Pharmacy Database and when that information will start to be provided to the subscribers of that file? (revised 7/1/06)

NCPDP has enhanced the database to provide the NPI among other data elements on pharmacies as in the past. Subscribers must modify their systems and obtain the NCPDP v2.0 Processor Set to receive the NPI. Please contact Jeannine Deese at ideese@ncpdp.org to begin receiving the v2.0 output file. The Pharmacy Database v2.0 Implementation Guide is available at http://www.ncpdp.org/frame_news_npi-info.htm.

Where can pharmacies learn more about NCPDP's progress with NPI enumeration? (revised 7/1/06)

The best place to learn the current status of NCPDP's progress with NPI enumeration is the NCPDP website. Go to www.ncpdp.org for information related to NCPDP's EFIO activities, updates to this FAQ document and applications. This will site be updated at least monthly. In addition, pharmacies will receive information periodically through NCPDP Now, e-mails, industry publications and other associations. If a pharmacy wishes to receive broadcast emails specific to NPI enumeration progress, please notify kdeininger@ncpdp.org and NCPDP will add the organization's email name to the broadcast email list.

Who should pharmacies contact if they have more questions?

Please e-mail Jeannine Deese, NCPDP Manager of Pharmacy Services at ideese@ncpdp.org. Please e-mail the question and it will be answered via return e-mail.



California State Board of Pharmacy

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834 Phone (916) 574-7900 Fax (916) 574-8618 www.pharmacy.ca.gov STATE AND CONSUMERS AFFAIRS AGENCY DEPARTMENT OF CONSUMER AFFAIRS ARNOLD SCHWARZENEGGER, GOVERNOR

To:

Licensing Committee

Date: November 27, 2006

From:

Board of Pharmacy

Subject:

Competency Committee Report

Test Administration Contract

The Office of Examination Resources (OER) within the Department of Consumer Affairs is seeking a new contract with a vendor to provide computer based testing through a Request for Proposal (RFP) process. The board uses this contract to administer the CPJE. The current contract expires December 1, 2006.

The second Request for Proposal (RFP) was cancelled effective November 8, 2006. OER has received approval to extend the current contract with Thomson Prometric to extend services from December 1, 2006, to May 31, 2007. A third RFP will be developed to begin services June 1, 2007.

CPJE Pass Rate Summary

A total of 1633 applicants took the CPJE in fiscal year 2005/06. Of the 1633 applicants, 325 failed the CPJE while 1308 passed the CPJE. The pass rate for the CPJE in fiscal year 2005/06 is 80%.

Competency Committee Structure Update

The current Competency Committee consists of representatives from different pharmacy settings. There are two board members, two board inspectors, 12 community practitioners, 10 institutional practitioners and four academic practitioners.

At the August meeting, the committee structure was bifurcated to increase the efficiency of the examination development. Since the committee restructure, each subcommittee has met once this year to work on exam development. The committee has set the dates for exam development meetings in 2007.